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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL

USES OF ISOTOPES

(ACMUI)

+ + + + +

WEDNESDAY,

FEBRUARY 20, 2002

+ + + + +

ROCKVILLE, MARYLAND

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The Advisory Committee met at the Nuclear Regulatory Commission, Two White Flint North, T2B3, 11545 Rockville Pike, Rockville, Maryland, at 8:00 a.m., Manuel Cerqueira, Chairman, presiding.

COMMITTEE MEMBERS PRESENT:

MANUEL CERQUEIRA, M.D., Chairman

DAVID A. DIAMOND, M.D.

NEKITA HOBSON

RALPH P. LIETO

RUTH McBURNEY

SUBIR NAG, M.D.

SALLY WAGNER SCHWARZ

COMMITTEE MEMBERS PRESENT (Continued):

RICHARD J. VETTER, Ph.D.

JEFFREY WILLIAMSON, Ph.D.

ALSO PRESENT:

JOHN W.N. HICKEY

ANGELA WILLIAMSON

SUSAN FRANT, Ph.D.

ROBERT AYERS, Ph.D.

MARJORIE ROTHSCHILD

PATRICIA RATHBUN

NANCY DALY

DONALD A. COOL, Ph.D.

PAUL LOHAUS

JAMES MYERS

WILLIAM UFFELMAN

CATHERINE HANEY

JOSEPH DeCICCO

FREDERICK BROWN

C-O-N-T-E-N-T-S

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P-R-O-C-E-E-D-I-N-G-S

(8:12 a.m.)

MR. HICKEY: Good morning.

PARTICIPANTS: Good morning.

MR. HICKEY: While we're waiting for Dr. Cerqueira, I'm going on the record to make the formal announcements of the meeting.

I'm John Hickey, Chief of the Material Safety Branch for NRC.

This is an open meeting of the Advisory Committee on Medical Uses of Isotopes. It's a transcribed meeting, and it's being conducted in accordance with the Federal Advisory Committee Act.

And we'll go off the record until Dr. Cerqueira gets here, and we'll begin the discussions.

(Whereupon, the foregoing matter went off the record at 8:13 a.m. and went back on the record at 8:15 a.m.)

CHAIRMAN CERQUEIRA: I'd like to welcome everybody, and I guess we have sort of a follow-up discussion from the Commission briefing yesterday. I'd also like to sort of reiterate the policy that we've adopted in the past for these meetings. I'd really like to generate action items.

In going through the material for today's

meeting, there's quite a bit of missing stuff there, and I'd like to avoid that in future meetings. What we really need to do is identify action items from the discussions, and then have clear follow-up.

And I think the discussion we had yesterday about making motions, taking a vote on something if we need to, which makes it a little bit more formal, and then I think as Dr. Williamson requested, perhaps sort of for the record getting some writing back from the NRC staff Commissioners on specific items that the Committee has brought to their attention just procedurally, I think, would be very important to do that.

And at some point during the day, hopefully before open discussion, but I think there were two issues that came up yesterday that we really need to sort of go forward with, and that's the issue related to the health physicist and the authorized medical physicist, radiation safety officers, in terms of trying to resolve some of these issues.

If it's, indeed, going to take a new rulemaking, then it's better to initiate the process now rather than waiting, and at some point I'd actually like to form a subcommittee that would look into these issues and then try to move it forward,

working with the staff and the Commissioners to try to identify the most expedient way to get the problem resolved.

I think it would be very important to do that.

As a result of yesterday's discussions also with some of you, some of you have close flights time-wise to catch, and we'll try to keep the agenda moving as much as possible, and I certainly don't want to cut anybody off during the discussions, but I think if people will sort of bear with me, if we're saying the same thing or people are perhaps taking too long to get to the point, I will sort of take the Chair's initiative and try to keep things moving.

DR. DIAMOND: Would you like us to suggest as a first motion today that we actually take a formal vote that as a policy we go and generate a list of action items for the result of our discussions, and that at the conclusion of that meeting each of those action items generates a written response from the staff?

CHAIRMAN CERQUEIRA: I think that's a good idea. Do we have a second on that?

MS. WAGNER SCHWARZ: I second.

CHAIRMAN CERQUEIRA: Okay. Any

discussion? John?

MR. HICKEY: If I could just state, the staff has no objection to that. In fact, that is our intent, that any resolution or action item will be responded to in writing and we'll do it in a format that, as Dr. Nag suggested, that a separate response provide responses just to resolutions and action items so that you don't have to wade through a larger document to provide those.

CHAIRMAN CERQUEIRA: And I will attempt to work with Angela Williamson to try to make these points, you know, basically so that we capture it, but I think if we make the motions, vote on it, she'll have all of the wording that's appropriate for it, and that will sort of trigger what items we need specific responses to.

Jeffrey?

DR. WILLIAMSON: Well, I was just going to ask: is there a mechanism for somebody to go through the transcript and identify all of these items? I believe that's been a problem in the past.

MR. HICKEY: Well, I think the answer to that is yes, but in terms of resources, I think it's better to make sure we identify them during the meeting. It's a problem for, you know, one person or

two persons to characterize what, in fact, constitutes an action item after the fact. It's better, I think, if we address that during the meeting.

CHAIRMAN CERQUEIRA: Well, again, I think if we end up taking a formal vote on it, that clearly is an item, and if there are other things that we're discussing and people feel that they want follow-up, I think it would be appropriate at the conclusion of the discussion to make a motion and take a formal vote on it.

That would make it very clear-cut for both the Committee as well as the NRC staff.

MR. HICKEY: Yes. If there is a vote, there's no question, but also if the Chairman and I, as designated official, just announce at the end of the discussion that we agree this is an action item, that also will be documented for the record.

CHAIRMAN CERQUEIRA: Sure.

Again, jeffrey.

DR. WILLIAMSON: Is it necessary to maybe appoint somebody as a recording secretary to make a list during the meeting of these items? It sounds like what you're proposing now.

CHAIRMAN CERQUEIRA: Somebody from the Committee, Jeffrey?

DR. WILLIAMSON: Not necessarily. It could be somebody from the staff.

CHAIRMAN CERQUEIRA: Perhaps Angela could.

MR. HICKEY: We already have a contractor making notes and a transcriber. We already have two people tracking the meeting. We've found that's an adequate mechanism, and in fact, we have a memo from the early 2001 meeting that responded to all of the items that were brought up in that meeting.

So we feel we have adequate tracking of this. As long as it's clearly stated in the meeting, it will be followed up on.

CHAIRMAN CERQUEIRA: Well, then perhaps it's my fault that I didn't sort of try to enforce that for this meeting, but I just didn't get the feeling that we've got specific action items that we need to get out.

I think the other thing that's important is the minutes of the meeting. I think all of us should look at those things ahead of time, and it's important to get it out I would say at a minimum of two weeks before the meetings. Is that a reasonable time?

Ralph.

MR. LIETO: I would just say all of that

is pretty much laid out in the bylaws of the Committee. We can just follow what our bylaws state, and I think that has the time lines and everything like that.

I think what John is suggesting is more than adequate for support.

CHAIRMAN CERQUEIRA: Okay. That sounds like it's a reasonable plan.

Any other follow-up from the Committee from the meeting with the Commissioners yesterday?

MR. HICKEY: If I could just add, Mr. Chairman, I also believe there was an important discussion on the amount of time it's going to take to implement the rule and if there's a six month deadline specified, the NRC staff needs to make sure the guidance is completed well in advance of that six month deadline.

There were several discussions of concern about that issue.

DR. DIAMOND: I'd also like to state that I believe the frequency of last meeting with the Commissioners in October 1999, I believe, was overdue and we should make a policy to do it more frequently than that, perhaps on an annual basis, and in an effort to aid with scheduling, perhaps we should go in

next year's Commission briefing as soon as possible so that we can best coordinate it.

CHAIRMAN CERQUEIRA: That's a good point.

But getting back to the initial discussion with the guidance documents, I think this is sufficiently important as we identified with debriefing yesterday. I'd sort of like to get a formal motion that guidance documents be completed in a timely fashion.

And you know, I asked the Commissioners would it be possible, but I think the Committee should go on record officially as saying that it's important to get the guidance documents out, you know, prior to the implementation and come up with a reasonable time period.

DR. NAG: Yes, I make a motion that the guidance document be at least three months ahead of the implementation, at least three months and not just a few days.

CHAIRMAN CERQUEIRA: So, John, a suggestion has been made and a motion has been put forward that -- do we have a second on the motion just procedurally?

MS. WAGNER SCHWARZ: Second.

CHAIRMAN CERQUEIRA: Okay, and so for

discussions.

You know, with Dr. Nag's motion, is three months realistic?

MR. HICKEY: Well, what I want to suggest is we hold the vote until the nine o'clock agenda item where we're going to be talking about the issuance of NUREG 1556, Volume 9, which is the guidance.

CHAIRMAN CERQUEIRA: Okay. I should have known that, but I didn't.

So, Dr. Nag, do --

DR. NAG: I will hold it.

CHAIRMAN CERQUEIRA: Okay. So we'll --

DR. WILLIAMSON: Mr. Chairman.

CHAIRMAN CERQUEIRA: Yes.

DR. WILLIAMSON: Could we vote? We have to vote on Dr. Diamond's motion, which is still on the table.

CHAIRMAN CERQUEIRA: That's true. We did.

DR. WILLIAMSON: So could we repeat the motion, what it is?

CHAIRMAN CERQUEIRA: Okay.

DR. DIAMOND: As **Action Item No. 2**, the Advisory Committee recommends that annual meetings be held to brief --

MS. McBURNEY: It was the other one. We

haven't even voted on the first one.

DR. DIAMOND: Oh, I thought we took a formal vote on it.

MS. McBURNEY: No.

DR. DIAMOND: I'm sorry. **Action Item No. 1**, the Advisory Committee recommends that during the course of each meeting a list of action items be generated expressing the wishes and the intent of the Committee, and that these action items generate a written and prompt response from the staff so as to demonstrate their feelings on the matter.

CHAIRMAN CERQUEIRA: Okay. I guess we've sort of all agreed to it, but perhaps a motion.

So a motion has been made, was seconded. There has been discussion. Any further discussion?

(No response.)

CHAIRMAN CERQUEIRA: If not, I call for a vote. All in favor.

(Chorus of ayes.)

CHAIRMAN CERQUEIRA: Opposed?

(No response.)

CHAIRMAN CERQUEIRA: No abstentions, and so, John, this will clearly be an action item.

And then we have still on the table the motion regarding the guidance document. So we'll sort

of defer that until after the discussion at nine o'clock by Susan Frant.

DR. DIAMOND: And that would bring us to **Action Item No. 2**, which was that the Advisory Committee recommend that annual briefings be held with the Commissioners to update them with the activities of this Committee, and that the Advisory Committee suggest that this date be scheduled as far in advance as possible so as to best facilitate the scheduling of that meeting.

CHAIRMAN CERQUEIRA: Do we have a second on that?

Second. Okay. Discussion? Jeffrey.

DR. WILLIAMSON: I think that is covered in our bylaws, that we have an annual briefing with the Commission. Is that not so?

CHAIRMAN CERQUEIRA: Yeah, I think Ralph's point is a valid one. The procedure is there, and it was included in the book this time, and so basically what we need to do is basically just get sort of compliance with the bylaws.

I guess the one issue that does come up, David, in terms of scheduling and appointment with the Commissioners, it's hard to predict the schedule. I think an attempt has to be made to have all five

Commissioners present, and so it's hard to figure out schedules, you know.

A year in advance may be difficult, but at least if we sort of, you know, try to get it as close as possible, that's reasonable.

MR. HICKEY: Well, Dr. Diamond said as far in advance as possible, which I think is reasonable. I don't think it will be done a year in advance, and if it is, it would be subject to change, but six months in advance certainly at least can be tentatively scheduled.

CHAIRMAN CERQUEIRA: All right. Dr. Nag and then Jeffrey.

DR. NAG: Well, one thing. I mean ultimately we should like to have the meeting with all the Commissioners, but if it fails, at the very least, we should have one Commissioner invited to the ACMUI meeting. One of the things that when we were informally discussing with the Commissioners after the meeting that we have a meeting, we have no problem if one of us comes to a meeting and at least be a representative.

So if a meeting cannot be held within reason, then we can do it by having a meeting with a, one or more, Commissioners.

CHAIRMAN CERQUEIRA: I just would like to get clarification. I think in the past when we've brought up that possibility, there is some rule for government committees, that we have to meet with all five Commissioners. John, am I hallucinating on that?

MR. HICKEY: I would have to check on that.

CHAIRMAN CERQUEIRA: Is there anybody from the staff?

MR. HICKEY: Our attorneys are here, but I don't know. I can check during a break to see.

DR. VETTER: Manny?

CHAIRMAN CERQUEIRA: Yes

DR. VETTER: I also received the message that Dr. Nag just reflected. One of the Commissioners mentioned to me that if at any time we would like to visit with one of them, we are free to invite them to come and meet with us as part of the meeting.

Now, that's not an official meeting with the Commissioners. That's inviting one of the Commissioners to come here to discuss an issue.

CHAIRMAN CERQUEIRA: Okay. I think that would be appropriate, and perhaps, you know, John, if we could get counsel to give us some information on this.

MR. HICKEY: We could include that.

CHAIRMAN CERQUEIRA: On what the rules are.

MR. HICKEY: Yeah, I might be able to get you an answer today, but if not, we could include that in the response to the resolution.

CHAIRMAN CERQUEIRA: Okay. But this is an action item. Hopefully by the end of the day, and if not by the end of the day, we should probably capture it.

Do we want to make a motion on this, David?

DR. VETTER: David already made the motion.

CHAIRMAN CERQUEIRA: Oh, he made the motion. There was a motion.

Okay. Just in terms of the meeting. Well, but there's several portion of it. One is the meeting with the Commissioners annually, but then there was the additional item in terms of infrequent meetings.

Okay. All right. So do we take a vote on the formal motion? We did to meet with the Commissioners, yes, and we didn't vote on it.

PARTICIPANTS: No.

CHAIRMAN CERQUEIRA: Okay. Any further discussion?

(No response.)

CHAIRMAN CERQUEIRA: And why don't you restate your motion?

DR. DIAMOND: Sure.

CHAIRMAN CERQUEIRA: And I think what Ralph is going to say is it's in the procedure, but it's just not being enforced, but I think this will at least identify it as something that needs to be addressed.

DR. DIAMOND: I'll try and restate then. **Action Item No. 2**, for the sake of the transcriptionist, would be that the Advisory Committee, in accordance with its bylaws, requested that an annual meeting be held with the Commissioners so as to update them on the activities of this Committee, and that this meeting be scheduled as far in advance as possible so as to facilitate this meeting.

Should the Commissioner not be able to hold this meeting, the Advisory Committee may invite as their guests to one of these meetings the Commissioners to attend for informal discussions.

CHAIRMAN CERQUEIRA: Okay. Shall we get

a second on that?

DR. DIAMOND: Do you want to -- wasn't that the sense? The sense was that we would try and do it in accordance with the bylaws. If that were not possible, that we would invite individual members to attend. Is that the sense that I had?

MS. McBURNEY: Well, I think we can do that anyway. I mean in addition to a formal meeting, we can.

CHAIRMAN CERQUEIRA: Invite them for specific issues that --

MS. McBURNEY: If it's not possible.

DR. DIAMOND: Okay.

DR. WILLIAMSON: I would propose amending it and deleting the clause --

CHAIRMAN CERQUEIRA: We don't have John Graham who is so great at making --

DR. WILLIAMSON: Well, we do our best.

MS. McBURNEY: That's right.

DR. WILLIAMSON: I would suggest an amendment that we drop the second provision of the motion, which suggests we could substitute a formal briefing with an informal visit. I don't think that's appropriate.

DR. DIAMOND: Okay. Would you like me to

restate it again with that amendment?

DR. NAG: But then what happens in the situation where all of us might not meet and where we never hold any meeting at all?

DR. WILLIAMSON: We'll just put pressure on the staff to -- you know, I don't think that all five of them have to be there. What is the legal requirement, three or four of them to hold a formal briefing?

MR. HICKEY: Three.

DR. WILLIAMSON: Three. So I think we have to be satisfied with that minimum, but I believe there's a legally quite different status according to a briefing than an informal visit, and we should take advantage of the formal briefing.

CHAIRMAN CERQUEIRA: So I guess in essence what we're saying is that, you know, we need to reinforce that there should be a briefing between the ACMUI Committee and the Commissioners on an annual basis as stated in the bylaws.

Is that the essence of what we're --

DR. DIAMOND: Yes.

DR. WILLIAMSON: Yes.

CHAIRMAN CERQUEIRA: So, David, do you want to make that your motion?

DR. DIAMOND: Sure. All right. Amended **Action Item No. 2** would be the Advisory Committee in accordance with its bylaws requests to hold an annual briefing with the Commissioners so as to update them with the Committee's activities.

In addition to this formal meeting with the Commissioners --

CHAIRMAN CERQUEIRA: Let's maybe take a vote on the formal meeting.

DR. DIAMOND: Okay.

CHAIRMAN CERQUEIRA: Okay. A second on that?

Second. Any further discussion on this?

(No response.)

CHAIRMAN CERQUEIRA: If not, we'll take a vote. All in favor?

(Chorus of ayes.)

CHAIRMAN CERQUEIRA: Opposed?

(No response.)

CHAIRMAN CERQUEIRA: Anyone abstaining?

(No response.)

CHAIRMAN CERQUEIRA: Okay. So we have that formal motion, and then --

DR. DIAMOND: And then **Action Item No. 3** would be in addition to this annual

Commissioner briefing, the Advisory Committee wishes to, from time to time, invite individual members of the Commission to join us for this meeting, period.

Jeff?

CHAIRMAN CERQUEIRA: Could we have a second?

DR. WILLIAMSON: That's not a motion.

CHAIRMAN CERQUEIRA: Well --

DR. DIAMOND: I'm trying to -- it has to be an informal meeting. It cannot be -- it's not a Commission briefing, of course.

MS. McBURNEY: But we can do that without a motion.

DR. WILLIAMSON: We can do that without a motion.

CHAIRMAN CERQUEIRA: Well, the reason we're doing the motion is to try to capture it. Unless there's some other mechanism by which we actually state that there's going to be a formal action item on this.

I mean, I don't want to get too formalistic on all of this, but I think this will simplify things a little bit in terms of getting feedback, and what I propose is in subsequent meetings --

DR. DIAMOND: I agree.

CHAIRMAN CERQUEIRA: -- we go back at the beginning of the meeting on these action items.

Ruth?

MS. McBURNEY: Well, I think it's pretty much a consensus of the Committee that we do that, and I'm not sure that a formal motion is necessary.

CHAIRMAN CERQUEIRA: All right, but then we want this as an action item.

MS. McBURNEY: Right, but as a consensus rather than --

CHAIRMAN CERQUEIRA: Okay. So for the transcriptionist, if you could somehow identify this.

MS. McBURNEY: That it's the consensus of the Committee that --

DR. WILLIAMSON: That we meet informally with the Commissioners as well as the formal briefing.

CHAIRMAN CERQUEIRA: Right. That the appropriate -- that the Committee request attendance at the ACMUI meetings of Commissioners who have an interest or "expertise" isn't the word, but what are we looking for, Jeffrey? Help me out here.

DR. WILLIAMSON: Okay, yes. The --

CHAIRMAN CERQUEIRA: John Graham in the making.

DR. WILLIAMSON: -- ACMUI desires that Commissioners who have an interest in the regulation of medical use of byproduct materials attend the ACMUI meetings on an informal basis.

CHAIRMAN CERQUEIRA: Okay. I think we get the sense of it, and we can see. You know, maybe, John, your staff could look at that and what the mechanism would be for us to invite -- I guess we could just invite them. I'm sure that there's some --

MR. HICKEY: Yeah, we can respond to that.

CHAIRMAN CERQUEIRA: Okay.

MR. HICKEY: When we call for agenda items, we can also get suggestions as to whether you want to invite a Commissioner.

CHAIRMAN CERQUEIRA: Okay, all right. Any other items in terms of the follow-up from yesterday's meeting?

DR. WILLIAMSON: Do we want to hold the item about creating a subcommittee and so forth for the Board certification until we come to that topic with Bob Ayers here or do you want to do that now?

CHAIRMAN CERQUEIRA: I propose we do that now, and then when Bob comes we can basically, you know, review that.

You know, in thinking about it, you know,

clearly it was an oversight on the part of the Committee. In talking to some of the former staff for the Committee, and I have to admit I don't recall the discussion, some of the issues related to this were we had long discussions about trying to make the training and experience requirements specific for the isotope, the technique as much as possible so that we didn't have somebody who had just kind of general training be able to operate on a system with which they had no familiarity.

And I guess some of the discussion amongst the staff had been how do we put some teeth into the fact that we needed training on specific equipment, and you know, that still needs to be addressed in terms of, you know, if you've got Boards, the Boards don't specifically require you to have experience with certain isotopes or devices.

And so how do we assure that somebody who has a general approval, i.e., Boards, meets some specific training requirements?

Richard, and then --

DR. VETTER: I don't think the proposed Part 35 answers that either because it says you're either Board certified or you have training, and it specifies the type of training, you know, 200 hours,

et cetera, et cetera.

So I guess without looking at -- having the words in front of us, I think what we need to take a look at is how we can change that regulation so that a person can be Board certified and have that specific experience without having the detailed listing of training and requirements incorporated into the Board.

Because, for instance, let's just pick ABMP for one board. For medical health physics, they require a Master's degree in the appropriate area, plus five years of experience, and you have to pass three exams.

But they don't say you have to have experience with HDR. So perhaps the direction we need to head and one of the alternatives, the Board certified plus that specific experience or at least some area of experience that covers most of those without prescribing that they have 200 hours in the following subjects because that's telling the Boards what they have to have for content.

That's the part that's problematic.

CHAIRMAN CERQUEIRA: Okay. Jeffrey.

DR. WILLIAMSON: Well, just a suggestion as a philosophical approach, how to address the issue I guess John raised, which is if NRC wants specific

training to be addressed, how could that be done.

So the approach could be to decouple the concepts of authorized user and authorized medical physicist from the required modality specific training requirements, you know, restore Board certification as the default pathway for AMP, AU, or RSO, and then in the appropriate subsections of 35, 35.4.600, for example, one could have in there as part of the operating procedures or regulations some kind of a requirement for continuing education in initial modality specific education.

MS. McBURNEY: In that modality.

CHAIRMAN CERQUEIRA: In that specific. Okay. So modality specific training.

DR. WILLIAMSON: So one might say, you know, for example, put in some kind of a regulation that captures the essence of the initial training that a physician who has no experience doing gamma stereotactic would have to undergo.

CHAIRMAN CERQUEIRA: I guess just in terms of what's been done to date now, is this something we could deal with in the guidance documents?

DR. WILLIAMSON: Potentially we could, but the desire of the staff -- I'm speaking for them now -- I think has been to avoid having de facto

regulations in guidance space and have them in regulatory space. So rather than have a separate set of de facto regulations in a licensing guide, which is now what we have, we have requirements for authorized user and authorized medical physicist to have some kind of training with HDR and gamma stereotactic, and that's done by license condition today.

And so I think the desire of the staff is to have essential license conditions mentioned in the regulations; is that not correct?

MR. HICKEY: That is correct, and I'm not sure, however, that even if we allowed for the guidance to be the determining factor that we could do it in this case because of the way that the rule is worded.

DR. WILLIAMSON: I think we're talking in the context of the rulemaking initiative, John.

MR. HICKEY: Okay. So you would have a rule change plus guidance?

DR. WILLIAMSON: We would have a rule change that would address the training and experience definitions of AMP authorized user and radiation safety officer, plus some supplementary changes in 35.600 that would address the NRC's concern about the AU and AMP not having modality specific specialized

training.

MR. HICKEY: Right, but then would you need guidance?

DR. WILLIAMSON: Well, you always need guidance, don't you?

MR. HICKEY: Well, no. But I mean would the substantive issue be dealt with by the rule change or would you need guidance to deal with the substantive issue?

Our intent -- my sense is we at least -- maybe we don't even need to talk about it. My sense is we at least need a rule change to deal with the substantive issue the way that the new Part 35 is worded now.

DR. WILLIAMSON: My preference would be to have such specifics of training probably in a guidance document rather than making a hard and fast rule so that at least individual institutions could negotiate the specifics of what their training would be.

MR. HICKEY: Okay.

CHAIRMAN CERQUEIRA: We'll go around, but so we've given up on the idea that there's any way we could do this within the Part 35 revisions. My typo comment yesterday was not --

MR. HICKEY: I wouldn't characterize

giving up on anything.

CHAIRMAN CERQUEIRA: Right. Well, but it's important because we could certainly expedite it if we could do it within guidance documents at this point, and who would know that, John? Would that be counsel? Would that be the staff?

MR. HICKEY: Well, I think I know, and I think some of the committee members know that the way the rule is worded, I don't think guidance can fix the problem.

CHAIRMAN CERQUEIRA: So we're saying we need a new rulemaking.

DR. WILLIAMSON: I think so, and we don't have to propose wording for the rule.

CHAIRMAN CERQUEIRA: Sure.

DR. WILLIAMSON: I think we should make a motion to the effect that NRC as soon as possible initiate rulemaking to restore Board certification for authorized user, radiation safety officer and authorized medical physicist as the default pathway.

CHAIRMAN CERQUEIRA: Well, just procedurally, you know, we're going to form a subcommittee, and it's going to work with the staff, and so maybe that will be the first step, but let's get some more discussion, and then we'll try to-- yes?

DR. NAG: I think the other thing, if we are going back to a rulemaking, it would be very important to -- the requirement for Board certification and the requirement for using in NRC. The reason is for the Board exam you need a certain body of knowledge, which is what the Board certification requires.

For example, you don't need gamma knife training to be Board certified, but the way we are making the Board certification, we are trying to push them to recruit all of these with training to become Board certificate. Rather than doing that, if we decouple (phonetic) them, a Board certification, the essential minimum required, and then if we are going to handle gamma knife or you're going to handle some of these specific things, you show your additional training that you had, which can be a very -- you know, the manufacturer's training or whatever. You supplement the Board requirement.

So if we are going to start from de novo, I think we should not be trying to push the Board to show you have training in all of these things. Otherwise we wouldn't allow Board certification to meet the de facto standard.

CHAIRMAN CERQUEIRA: Now all of the

discussion has really dealt with therapeutic radiation. I mean, do we feel that as written, the diagnostic requirements are okay?

MR. HICKEY: Mr. Chairman, I think there is an issue with the statement about a preceptor. I'm not sure that all of the certification Boards understand that the rule requires the preceptor statement be part of the Board certification process.

So as far as what training and experience the people have, I think the rule is okay, but I think there still is an issue with the requirement for a preceptor statement.

CHAIRMAN CERQUEIRA: I thought the preceptor statement was pretty clear. It had to be, you know, an authorized user who basically signed off on having been exposed, and in addition, being competent.

We spent quite a bit of time discussing that. We're trying to put more teeth or more liability upon the preceptor's statement, and let them, you know, assume some responsibility for the people that they're signing letters for.

MR. HICKEY: Yes, that's correct, and there are already requirements in the old Part 35 for preceptor statements. I'm just not sure whether the

Board that certifies the person requires the preceptor statement as part of the certification process or whether they view that as another step.

CHAIRMAN CERQUEIRA: Well, I think when I guess Bob is going to be presenting things this afternoon -- so we can get back to it.

Richard.

DR. VETTER: Just to confirm what John just said, at least in the physics are, radiation safety officer area, the Boards feel that is a separate process, the preceptor statement. They do not require a preceptor statement for the Boards.

MS. McBURNEY: Right.

MR. HICKEY: Yeah, that was clear for the American Board of Health Physics. I'm just not sure whether the Medical Boards have that understanding.

CHAIRMAN CERQUEIRA: Jeffrey?

DR. WILLIAMSON: For American Board f Radiology and American Board of Medical Physics, and I think this covers radiation oncology, as well as physics, there is a requirement. It's part of the application process that letters from diplomates of the Boards attesting to the competence in character of the applicant be made.

But I do think there is a legal problem

here because it really doesn't say that these individuals have to be authorized users or authorized medical physicists on an agreement state or NRC license.

So I believe John may be right that even though there is sort of a preceptor requirement associated with many of these Boards, I'm not sure it complies with the letter of the law.

DR. NAG: One other problem with that is there is the preceptor statement, but that's done by the director of the training program. It does not make separately in all of the areas. You know, I will certify that I have trained him in radiation oncology, but not a separate statement that can handle unsealed isotope; he can handle, you know, each of those things separately.

CHAIRMAN CERQUEIRA: All right. Who are the stakeholders in this now? We've talked about authorized medical physicists. We've talked about radiation safety officers.

DR. NAG: Authorized users also.

CHAIRMAN CERQUEIRA: Okay.

DR. NAG: It depends on which, definitely of authorized users.

CHAIRMAN CERQUEIRA: For diagnostic or

therapeutic?

DR. NAG: Therapeutic.

CHAIRMAN CERQUEIRA: Okay.

MR. HICKEY: I think that all of the Boards have a potential stake. They're on the record as of today as saying that there's not a problem with the rule, but in looking at the preceptor issue, I think on second review there may also be a concern. They're not on the substance of the training but on the requirement for a preceptor statement.

CHAIRMAN CERQUEIRA: Rather than -- you know, because we have Bob Ayers here, who's kind of part of the NRC staff that's looking at this, maybe we can conclude this discussion and bring it up with Bob. But I think there was a motion to form a subcommittee that's going to look at the issue of training and experience.

Initially we were talking about the authorized medical physicist, the radiation safety officer, and the authorized medical user with therapeutic. So I think forming a subcommittee that would have, you know, members from those various groups, plus maybe one or two other people, would be important.

Ruth?

MS. McBURNEY: Richard or Ralph, correct me if I'm wrong, but I think there is a model for the rule of decoupling the Board certification from additional training required for the different modalities under MQSA. Isn't that right that they accept Board certification as the training for the medical physicist, but then if you're going to be doing a different modality, you need additional continuing ed. for that?

DR. VETTER: I think that's correct.

MR. HICKEY: Could you identify that organization for the record, please?

MS. McBURNEY: The Mammography Quality Standards Act under the Food and Drug Administration.

CHAIRMAN CERQUEIRA: All right. Well, so I propose that maybe we have Jeffrey, Dick, you know, be on this committee, and since Dick has more gray hair that Jeffrey, maybe we could let him be the chair of this committee.

And I think we should get a radiation oncologist. David, is that something --

DR. DIAMOND: I'd be happy to do it, sure.

CHAIRMAN CERQUEIRA: So maybe David could be on that committee, and I guess maybe we're going to add two new members to the committee. I guess we have

to vote on them at this meeting.

MR. HICKEY: No.

CHAIRMAN CERQUEIRA: What's the time line? We've gotten approval.

MR. HICKEY: No. The selection for the two vacancies is still in process, and as Commissioner McGaffigan mentioned yesterday, well, we have to appoint a nuclear medicine physician to fill a vacancy, and then as Commissioner McGaffigan mentioned yesterday, we're going to add an interventional cardiologist at the direction of the Commission, and those are in process.

So we think prior to the next meeting you'll have those appointees.

CHAIRMAN CERQUEIRA: Right, but I was sent a list of people who had been nominated, and they were -- you know, by professional medical societies, and the NRC staff had sort of sent me the names of two individuals for those positions, and I basically concurred that I thought --

MR. HICKEY: Well, that's still in process. We can't have anymore specific public discussion while that's still in process, but the process has not yet been completed.

CHAIRMAN CERQUEIRA: But why is it taking

so long?

I think one of the things we had discussed was basically trying to facilitate, and Angela certainly made a --

MR. HICKEY: Yes. The reason that the interventional cardiologist is not complete is because that's fairly recent. The nomination period, I believe, did not close until January for that one, and the other one has been delayed by the other things that the Commission has been dealing with following 9/11 or it would have been resolved.

CHAIRMAN CERQUEIRA: Is there any way we could fast track it, John? I mean, in a sense, you know, the professional societies have made nominations. They've been reviewed by the NRC staff. They've been sent to the committee chair who basically agreed with the staff on these people.

MR. HICKEY: Yes. We're doing every -- I mean, you can form an action item or resolution, but we're doing everything we can to complete that process.

CHAIRMAN CERQUEIRA: Well, I guess I don't fully understand why it's taking so long. I mean, we had discussions to try to minimize the lag time between a vacancy and filling it.

MR. HICKEY: Well, as I said, the interventional cardiologist one should be completed within 60 days of the nomination period closing, which I think is reasonable, but the other one has not been timely. I agree.

CHAIRMAN CERQUEIRA: Okay. So give me a time line then. Where do we stand?

MR. HICKEY: I would say within 60 days we'll have an announcement on both, but again, the Commission has to review these. So that's assuming the Commission responds promptly, which they have done in the past on these.

CHAIRMAN CERQUEIRA: And I guess, you know, all of these things like security checks and everything will be all --

MR. HICKEY: That can be done afterwards.

CHAIRMAN CERQUEIRA: Okay. You know, it's a little disturbing because we really had emphasized at the previous meetings of trying to minimize the time between people going off and new people, and I had every expectation based on the material that I had been sent that we would have people in these positions, you know, at the end of this meeting.

So Dr. Nag?

DR. NAG: At the same line, anyone who

will be moving off about a year from now, we should be starting the process from now. So anyone from this committee who is supposed to be going off about a year from now? Do we have anyone?

DR. DIAMOND: Jeff, how much longer? ARE you in your second term? Is that right?

DR. WILLIAMSON: I think so.

DR. DIAMOND: You're in your second term.

MR. HICKEY: I think everybody is going at least until 2003, but we agree that we need --

DR. NAG: One year.

MR. HICKEY: -- to plan better on these.

CHAIRMAN CERQUEIRA: Well, what I would like to do is at least get a list of just Committee members, when they came on, whether it's first term, second term, and when their term expires, and distribute that to the Committee.

MR. HICKEY: Yes, we have that. That's already made. We can copy it and give it to you.

CHAIRMAN CERQUEIRA: Well, if somebody could --

MR. HICKEY: We can give that to you today.

CHAIRMAN CERQUEIRA: -- just give it to us today.

MR. HICKEY: yes.

CHAIRMAN CERQUEIRA: That would be useful.

DR. WILLIAMSON: We can make plans.

CHAIRMAN CERQUEIRA: But again, I'd really like to, you know, identify the fact that the Committee has been moving forward. I certainly have dealt with some materials sent to me, and I think in order for the Committee's work to be done, we certainly need a nuclear medicine representative, and I think we've agreed that an interventional cardiologist is an important, you know, member of the Committee, given some of the things that are going to be coming up.

And so I think we need to move forward as quickly as possible to get these people appointed.

Jeffrey.

DR. WILLIAMSON: So with regard to the subcommittee, the charge is to --

CHAIRMAN CERQUEIRA: Okay. Well, again, I got sidetracked there. So --

MR. HICKEY: Well, let me just interject that some of these items have been useful because we intended to take them up later in the day, and we'll save time later on having discussed them now.

CHAIRMAN CERQUEIRA: Okay. That's true,

but still I think, you know, we've identified three people. I think it would be important if we're going to deal with the whole issue of intravascular brachytherapy if we could have the interventional cardiologist be part of that committee. That would be useful.

That would bring us up to four people, and it's always good to have somebody who's not necessarily a stakeholder on the subcommittee, i.e., Ruth or Niki. Niki is pointing, but, Ruth, would you be willing to?

MS. McBURNEY: I certainly would.

CHAIRMAN CERQUEIRA: Okay. So I think the committee would then consist of Jeffrey, Ruth, Richard, and David Diamond with Richard acting as the subcommittee chair.

And the charge of the committee -- and I think we could have a little bit of discussion on this -- but basically, you know, would address the issue of training and experience for authorized medical physicists, authorized physician users, and radiation safety officers, and you know, really look at the whole issue of the Boards and the training and experience, trying to deal with both, you know, kind of general, as well as specific training.

And maybe we could spend a few minutes trying to fine tune the charge to the committee.

Jeff and then David.

DR. WILLIAMSON: Well, I'm wondering if it would be useful to have some staff members also be on this subcommittee. I think this is so highly juridical that I wonder if the attorney from NRC shouldn't join us and one of the staff members who's conversant with these issues.

MR. HICKEY: As a procedural matter I don't think that's a good idea. I think the subcommittee needs to speak for the ACMUI, but we will designate contacts, both technical and legal contacts, for the subcommittee to work with on a day-to-day basis.

DR. WILLIAMSON: Good.

CHAIRMAN CERQUEIRA: So I think it would be good within two weeks to have those people identified so that Richard could make contact with the people and, you know, to try to get some useful information to at least define what the requirements for sort of new rulemaking, to explore the possibility can any of this still be done under the revised Part 35, which we're all working on under the assumption that it's going to be implemented in six months, or do

we need to go to new rulemaking, which it's Jeffrey's feeling, and I concur with him, it probably will be required.

David.

DR. DIAMOND: My sense is just as I'm thinking about this is that this subcommittee is really going to be looking at a new rulemaking initiative in which there's going to be a sense that we restore Board certification in a parallel structure as the default pathway for the AMPs, the RSOs, and in this process attempt to decouple general from overly prescriptive site specific or modality specific training, which will give us the flexibility that we need to address new technologies, which will be parallel amongst these different fields, and which will go and maintain the status of the Boards as the premier methodology for expressing to the public an individual's competency and safety in performing the task.

I would also like to point out as an aside it's very important that the staff understand that any time -- and I'm only speaking for physicians now because that's my area of expertise -- any time a physician is desirous to obtain a hospital privilege to perform a specific modality, regardless of the

Board certification, they need to prove to the hospital that they do have a certain experience in that particular field.

So, for example, if one wanted to do stereotactic radiosurgery as a physician, before a hospital would grant a privilege to do that, there is always a final safeguard in effect that you must prove to the bylaw committee or the credentialing committee that you have that, and that goes on for many, many different areas.

So just since you may not deal with this in your particular role or practice, it is important for you to know that there is another set of safeguards in effect to protect the public in these very specific modalities when it comes to the public.

DR. WILLIAMSON: For example, at Washington University, the radiation safety committee also serves as an independent safeguard in this respect because our license mandates certain annual training be given to authorized users and AMPs for gamma stereotactic and for HDR as a condition of our license.

And so they monitor that, and there are separate lists of authorized users and AMPs for these different modalities.

DR. DIAMOND: Jeff, would you concur with my general sense that I was trying to convey? Was I on track basically with the parallel structure trying to keep the Board as the premier pathway and so forth?

DR. WILLIAMSON: Yeah, absolutely.

CHAIRMAN CERQUEIRA: I think we're starting to get into the specifics, and I think sort of the discussion is to form the committee, and we've agreed that the subcommittee consisting of Dr. Williamson, Vetter, Diamond, the interventional cardiologist who will come on the Committee, and Ruth McBurney, and I kind of hate -- you know, you kind of want to give a charge to the committee rather than having the committee come back, you know, with what they're going to do.

But the basic charge is to develop --

DR. WILLIAMSON: A draft rule.

CHAIRMAN CERQUEIRA: We need John.

-- draft rule for what? For?

DR. WILLIAMSON: Yeah, so to develop, you know -- a subcommittee would be charged with developing the outline of a draft rule to restore --

CHAIRMAN CERQUEIRA: Just something general. A draft rule --

DR. VETTER: I think that captures it. A

draft rule to capture what Dr. Diamond had said.

CHAIRMAN CERQUEIRA: But that was too much. Who can remember that?

DR. DIAMOND: We can do it in one sentence.

DR. WILLIAMSON: The subcommittee's charge is to develop the concept of a draft rule that restores Board certification as the primary pathway for becoming authorized user, authorized medical physicist and radiation safety officer.

CHAIRMAN CERQUEIRA: All right. Does that sound like a motion?

PARTICIPANTS: Yes.

CHAIRMAN CERQUEIRA: Second?

MS. WAGNER SCHWARZ: Second.

CHAIRMAN CERQUEIRA: And any further discussion?

MR. HICKEY: I have a comment and a question, Mr. Chairman. The committee is time is of the essence, and this has high visibility with the Commission now. So I will tell Dr. Vetter right now I will be the contact. I will let you know who other contacts are, but two weeks is not going to go -- this isn't going to sit for two weeks.

We're going to be continuously working on

this between now and the time the rule is published.

CHAIRMAN CERQUEIRA: All right, but we don't anticipate that we're going to be able to get this resolved and certainly with the rulemaking, but I think, you know, basically we've formed a committee, and we should have them come back to us at the next meeting.

So a motion has been made. We've had a second. Any more discussion?

(No response.)

CHAIRMAN CERQUEIRA: Okay. I call for a vote. All in favor?

(Chorus of ayes.)

CHAIRMAN CERQUEIRA: Opposed?

(No response.)

CHAIRMAN CERQUEIRA: No one is abstaining. So all right.

DR. DIAMOND: That was **Action Item No. 4,** then.

CHAIRMAN CERQUEIRA: Right.

MS. HOBSON: Did you mean like our next ACMUI meeting?

CHAIRMAN CERQUEIRA: To come back and give us at least a progress report on, you know, some of the issues and sort of a game plan.

MS. HOBSON: Well, I felt a sense of urgency that we need to move faster than that if possible, you know. Was I reading it wrong?

CHAIRMAN CERQUEIRA: No. I guess part of the question is I don't know, you know, what's involved in the rulemaking process. I mean, having been involved in Part 35, which is, in a sense, you know, NUREGs --

DR. WILLIAMSON: I think our charge is sufficiently open ended that, you know, we're not locked into any specific time frame. So I think this is just great. If the staff is geared up to move fast on this, we're going to support and help them.

CHAIRMAN CERQUEIRA: One last comment from Ralph, and then we have to move on.

MR. LIETO: I have a question for John since this is a subcommittee of the Advisory Committee that's working on this. Is it acceptable that if they come back -- say they have something to present within the month. Does the full Committee have to vote on that? And if so, can it be done by electronically via E-mail?

MR. HICKEY: Yes. The actions can be done by E-mail or by telecon. and, in fact, I think we're going to have to plan on doing a lot of that.

CHAIRMAN CERQUEIRA: Yeah, I would recommend that we don't necessarily need to have face-to-face meetings.

Okay. All right. So I think we've dealt with most of the procedural ways we would like the Committee to proceed in the future. We've discussed the Commission briefing, and maybe we can go on to the NUREG 1556, Volume 9.

MR. HICKEY: Mr. Chairman, Dr. Susan Frant is here. She's the Deputy Director of Industrial, Medical, and Nuclear Safety.

DR. FRANT: Hi. They even got a name tag so that in case you forgot me.

(Laughter.)

DR. FRANT: And I have one for me so that in case I forget.

Good morning. I've met some of you individually, but not all of you as a group. So I'm happy to be here this morning.

I've been with the Industrial Nuclear Medicine Safety -- I think those are all of the words for the division -- since April. Before that I worked as a deputy for another division in NMSS, and before that, I was in Region I, which is the northeast, as the deputy that had licensing of medical licenses.

So I have a little familiarity, but not a lot, and I come to this area with maybe a different perspective than some of the folks who have been working in it.

Part 35. We've been working on how we're going to implement it, and we've been standing at the starting gate for a long time waiting to kind of okay, okay. As you know better than I, that has been a torturous time to get it into a position where it's going to be published and going to be final.

And I gathered from the meeting you had with the Commission yesterday that there are still some issues that are significant that are not settled by the current final rule as it will be published. And the Commission certainly pledged that we will work through those issues in a timely way.

And the discussion I heard when I came in was one of the mechanisms to do that, and I'm glad that you'll have a subcommittee, and if you draft language, it doesn't have to be exactly rulemaking language, but if the language is what will work to have qualified people who can protect the public in terms of radiation safety doing the procedures, regardless of whether we know what they are today or they come on the horizon, that will be, I think, a

significant move forward for Part 35 as it stands.

In terms of what we're doing now to move forward in implementing Part 35, I can tell you what we're doing and take hopefully some suggestions from you on how ACMUI can be most involved effectively for us and for you and efficiently for us, hopefully efficiently for you, too.

CHAIRMAN CERQUEIRA: Susan.

DR. FRANT: Yeah.

CHAIRMAN CERQUEIRA: If I could just interrupt for a minute now, so we're talking about the guidance documents in part.

DR. FRANT: We're talking about implementing Part 35 so that we --

CHAIRMAN CERQUEIRA: Right, which includes guidance documents?

DR. FRANT: It includes guidance. It includes inspection, and let must briefly go through --

CHAIRMAN CERQUEIRA: Sure. Go through.

DR. FRANT: -- and then after I run through this, then you can ask me questions, and we can talk about --

CHAIRMAN CERQUEIRA: Is there a handout or slides on this?

DR. FRANT: No.

CHAIRMAN CERQUEIRA: No?

DR. FRANT: No.

CHAIRMAN CERQUEIRA: Okay.

DR. FRANT: As you know, we have Volume 9 of the consolidated guidance, the 20 volume set that we've pulled together over the last -- I don't know -- several years, and Volume 9 identifies those aspects that would be necessary to be licensed under Part 35.

And the current draft Volume 9 responds to all of the comments that were made on a draft that went out with the proposed rule and reflects the changes made to Part 35 from the proposed rule to the final rule.

And I think you've seen that, have you not?

MS. WAGNER SCHWARZ: Yes.

DR. FRANT: Yes. Okay. It still has many things in that I would say are highly prescriptive. The phrase that some people have used is that there's a group of practitioners who might need "Part 35 for Dummies," that is, a very detailed, pick your hand up, move it here, do this.

I think that that is very different from other aspects of NRC that I've been involved in. In

the reactor world that I was in for 20 years, we never put out procedures. We always left it to licensees to develop procedures to implement the regulations.

And I have to tell you that it was kind of strange for me to see these model procedures. At the same time, the staff who have been working with this, I think, believe that there was a very strong need for this by some practitioners.

So you have a tension between providing detailed guidance and allowing mature professionals to choose the way in which they're going to implement regulations.

I think we're trying to strike that balance, and to do that, we're going through Volume 9 now with an eye towards making it a basic document and taking these model procedures and perhaps putting them in some other form.

It would be good, I think, if the societies in the community would help us do that, and maybe it would have been better to have joint documents, which we've done in other -- I worked with NEI and I've worked with other groups where we've put out joint documents.

For a long time I was responsible for training and procedures in the reactor world, and the

Institute of Nuclear Power Operations developed the guidelines for training programs, and we endorsed them. So we had a joint document that was basically developed by the industry and then reviewed and accepted as an acceptable way to implement the regulations.

There's no reason why we couldn't do that here, too, but it requires a commitment on the part of the community to do some of the work. And I'm not sure. I don't know where we are with that.

To that end --

CHAIRMAN CERQUEIRA: Well, if I could --

DR. FRANT: Yeah.

CHAIRMAN CERQUEIRA: -- I think the community is willing to work, but there's a time frame that's involved, and if we haven't initiated the process, I don't know realistically --

DR. FRANT: Well, let me tell you what.

CHAIRMAN CERQUEIRA: Sure.

DR. FRANT: I don't know how many of you know Chip Cameron, but I know he's worked with Part 35. So Chip and I have worked together on many things over the years, and what we discussed was taking the current Volume 9, making some modifications -- and Roger Brotus who's sitting in the back is taking a few

minutes out of his schedule where he's totally immersed in Volume 9, with a small cadre of folks -- to make some modifications, but to get it out by March 15th as a document for comment.

At the same time, Chip and I will be having a planning meeting on March 14th to plan for two public meetings, actually three, I think. One meeting would be some kind of a workshop on Volume 9, the totality of it.

A second -- probably these are both at the end of April. One is planned for April 23rd, and the other is planned for April 30th. The second meeting would be on guidance, some kind of diagnostic only guidance that would be just a few pages that would focus on what the diagnostic practitioner would need to know and would not have all the volumes of material that deal with all the variations within the therapeutic community.

That guidance, I think, to the extent that we can get help and maybe produce a joint document, that would be excellent. If we can't, maybe we'll take a crack at it and have it reviewed, the point being that there would be two documents. There would be Volume 9, which would cover everything to implement Part 35, and that's necessary and we have to have

something like that.

But then there would be this subset, and it may be that the therapeutic community or parts of it feel that there should be some stand alone documents for other than diagnostic, and we can work those out in the future.

I'm not precluding them. It's just in terms of time, they seem to be the things that are most needed now.

We also plan to develop inspection procedures, and I think from the discussions yesterday and what I know about the way NRC does business, this will be clear to having a clear message of how Part 35 represents some kind of paradigm shift.

We also plan on conducting training for both our license reviewers and our inspectors, and we'll be doing that in late May based on the guidance documents and the public meetings. And I already have that set up with a woman named Bev Silverberg.

Do any of you live in Washington? Oh, no. Okay. Well, Bev was the voice of Metro. She used to be the one that would come say, "The trains are running, and it's okay." But anyway, only in snow storms mostly.

Anyway, Bev has been working with NRC for

a long time, and she does a really good job in terms of helping people get the message across. So we are going to take people, and we have a Part 35 team that we've developed, people who will become the trainers.

MS. McBURNEY: A question. Will this training also be available to agreement state personnel?

DR. FRANT: Sure, sure. And we'll probably set it up in the four regions and invite appropriate agreement states at the same time. I don't know why we can't do it concurrently. Sure.

So that's our plan, is to train the trainers some time in late May, and then hold a workshop on inspection guidance; finalize the inspection and licensing guidance, and of course, that will include ACMUI participation, and we can talk about at what key points and at what point you want to be in a review mode, at what point you want to be in a comment.

You know, I think there are lots of roles to be played, and then we'll do our regional training in June through August, depending on when -- hopefully that will be on finalized guidance, but certainly guidance that's close to final.

So that what we're working towards is an

October implementation date in which we will have final licensing guidance by the end of spring; final inspection guidance also by the -- this is the government. So if I say late spring that could be July, you know -- but we'd be working -- you know how you write "late spring"? Okay.

But the goal is to have the training over the summer based on the finalized guidance and inspection procedures, and what I heard yesterday in the discussion with the Commission is it may be that we have to have a transition period, and when they're enforcement discretion, and we work our way through that guidance and some of the issues that may come up as we look at the rule when it's real, so to speak, you know.

And I don't understand. I hope to learn more about how the training and education issues are evolved, but there they are, and so we have to fix them. There may be others that we find that we have to fix.

So that's our plan. It's looking towards an October implementation effective date, but some questions have come up, and we're working through them now. Some applicants for renewal have already said, "Can I be renewed against the new Part 35?"

Well, no, you can't be renewed against something that doesn't exist. It's not published. On the other hand, you can be in timely renewal, and we can look at what it would look like once it's published, but it can't be effective until it's effective.

So that's a simple answer, you know. It can only be soup when it's soup, but on the other hand, you can't deny the fact that you can see what's coming on the horizon. So you try to work that, and we'll work that through.

We have a counterpart meeting tomorrow with the Regional Division Directors, and these are some of the issues I've got to talk through this schedule with them, get their comments, and the reason there's no handout, Dr. Cerqueira, is because I wanted to keep it fluid enough to get comments from you all, comments from the Regional Directors, and have a schedule that everybody can work with and live with, and get to the implementation date with guidance that's workable in hand, inspection procedures, license reviewers, and inspectors trained and thinking new Part 35 with the performance based, risk informed mindset.

CHAIRMAN CERQUEIRA: Susan, that's --

DR. FRANT: I was glad the Commissioners were so confident we could do it.

CHAIRMAN CERQUEIRA: Well, this has been an excellent presentation in the sense that you've given us details. You've given us dates, and I think this is tremendous.

I think it would be helpful if perhaps, you know, when you've had a chance to sort of -- certainly some of these dates we've been writing down, but if we could get an E-mail or a copy of these out to the Committee --

DR. FRANT: Of course.

CHAIRMAN CERQUEIRA: -- that would be very useful.

I'd also like to --

DR. FRANT: I'll get it to Angela, who will get it to you al.

CHAIRMAN CERQUEIRA: Yeah, that would be useful.

I'd also like to say that, you know, we had these writing pads yesterday, and they've gone for some reason. All I've looked around and everybody is trying to write notes on these yellow pads.

So, Angela, what happened to the white -- they were here yesterday.

MS. WILLIAMSON: Oh, it was the Commissioners.

DR. NAG: In the Commissioner meeting.

CHAIRMAN CERQUEIRA: Well, it would be nice, especially since if we don't have notes --

DR. FRANT: Well, Angela is off. We have a supply room and --

CHAIRMAN CERQUEIRA: Good. Okay.

DR. FRANT: You know, we've been on a tight budget, but I think we --

(Laughter.)

CHAIRMAN CERQUEIRA: No, I think that would be helpful.

But, again, you've done a great presentation, and if we can live up to those time lines, that would be ideal. And I think you're bringing in an approach certainly from the reactor area which I think would work well within medical. And I think if we could implement that, that would be great.

DR. FRANT: Let me ask you. The planning meeting on March 14th, I would like someone from ACMUI, if it's possible, to be part of that planning meeting with Chip and with myself so that we could have your insights on who should be included in these

meetings.

You know, Chip has a way of running the meetings, and he's very inclusive, and he's already made some phone calls. I don't know if he's talked to any of you, but --

CHAIRMAN CERQUEIRA: I don't think any of us have been contacted about the meeting. I mean, March 14th is fairly close, but we certainly would, you know, try to get a representative there. Since I'm only a bus ride away, I could almost do it.

But I think it would be important, again, if -- the Committee wants to be involved in these kind of things, and the more notice we have, the better.

Now, do we have questions? Jeffrey has been --

DR. FRANT: I'm sorry.

CHAIRMAN CERQUEIRA: -- chafing at the bit here.

DR. WILLIAMSON: No, that's okay. Well, I think that, as you know, the issue of training experience and Board certification is sort of a mess, and I guess you will be responsible for drafting the guidance that the regions will be using to determine under the existing rule as written --

DR. FRANT: Right.

DR. WILLIAMSON: -- how to basically work through all of these problems of deciding how a Board certified physicist or physician needs to qualify for the different modalities.

So I think there's an opportunity to ameliorate this circumstance by trying to write reasonable guidance which would take into account existing Board certification, satisfying many of the requirements and having a realistic requirement for supplementary training beyond Board certification.

DR. FRANT: Right.

DR. WILLIAMSON: Which comes close to what we do in the field.

DR. FRANT: I guess you all know Bob Ayers, and he'll be talking to this. When, Bob?

DR. AYERS: One o'clock.

DR. FRANT: Okay. One o'clock, and he and I have been talking about what kind of mechanism we could develop that would allow for some relief while there's a rulemaking in progress, and that that needs our Office of General Counsel to sort of help us understand what options are available that are all within, you know -- I could speculate. I mean, there are several of them, and this isn't the first time that there has been a need for some kind of relief

related to a regulation.

So that we have some mechanisms and will have to come up with one and maybe, Dr. Williamson, you can help us. If you're working on draft language, then we can also talk about how that would -- what we would do in the interim to --

CHAIRMAN CERQUEIRA: I don't know if you captured the discussion that we had before you came on, but we are sort of forming a subcommittee.

DR. FRANT: Right.

CHAIRMAN CERQUEIRA: And then looking at the ways to address the issue.

DR. FRANT: But the permanent solution is rulemaking to amend the current -- no, rulemaking to amend the not current, but soon to be Part 35. Okay.

CHAIRMAN CERQUEIRA: Other questions for Susan? Niki.

MS. HOBSON: Well, you probably told us and I just missed it. You're going to have the revised document out for comment by about the middle of March?

DR. FRANT: Roger? Yes.

MS. HOBSON: And then when do you expect to have the final document ready for publication or whatever you do with it so that the users --

DR. FRANT: Right.

MS. HOBSON: -- out there will know what they're up against?

DR. FRANT: Exactly. I think though, just to be clear, the rule will be published at the end of March, and it's the rule that you have to comply with.

So one of the things that we're going to have to say in the guidance is that it's guidance on one way to comply with the rule, and that what a licensed reviewer has to make sure that you're doing is complying with the rule, not the guidance.

That's an important part of the way we implement our rules.

Marjorie, did you?

MS. ROTHSCHILD: Marjorie Rothschild from the Office of General Counsel.

Just a couple of things. First of all, I think the Commission's intent is to publish the rule in mid-March 30 days from the submission of its report to Congress, but you know, that's not a certain date because it's possible that, you know, we could hear otherwise from Congress.

So I just wanted to make sure. That, I think, is the Commission's intent, but it's not entirely certain or up to the Commission.

And one other comment I just wanted to make. In terms of meeting with a Commissioner, I think some lines may have been blurred in terms of if committees are just talking about inviting Commissioners to their formal meetings. That's one thing, but I think it's another issue if you're talking about the Committee in whole meeting, you know, privately with a Commissioner.

So I just want to -- I think --

CHAIRMAN CERQUEIRA: Yeah, I don't think that was our intent to have private meetings.

MS. ROTHSCHILD: Yes.

CHAIRMAN CERQUEIRA: It was basically to have them show up at a session like this to get their specific input or to, you know, address issues that are of concern to the Committee directly.

MS. ROTHSCHILD: Right. Well, that's what I assumed, but I just thought it maybe needed to be said just once again.

And then as far a any future rulemaking, there are different means for initiating rulemaking, but we just have to be aware that there are certain procedures and limitations actually as far as staff contact if you were talking about a, you know, petition for rulemaking from outside parties.

So I just wanted to emphasize that once again. I think it may not, you know, have been as clear possibly in some of the earlier discussions this morning, but I just wanted to clarify that.

Thank you.

CHAIRMAN CERQUEIRA: Okay. Thank you.

DR. FRANT: Everybody knows Marjorie Rothschild.

CHAIRMAN CERQUEIRA: I think she should actually have a seat at this table here because --

DR. FRANT: Right.

CHAIRMAN CERQUEIRA: -- so many of these issues would be -- you know, if we could address her directly it would be -- but we can call on her, can't we, John, if we have --

MR. HICKEY: Yes. That can be arranged. We have another microphone up here.

CHAIRMAN CERQUEIRA: Yeah, well, definitely because it would save us quite a bit of time on, you know, just some of these procedural issues

DR. FRANT: Okay. Well, the planning meeting March 14th, I think it would be good if you had somebody at that meeting.

CHAIRMAN CERQUEIRA: What's the time of

the meeting?

DR. FRANT: I'll have to get back to you.

CHAIRMAN CERQUEIRA: Okay.

DR. FRANT: I know the room, but we'll probably spend a good portion of the day.

CHAIRMAN CERQUEIRA: Again, if Angela could get an E-mail out to people with time and location, and we should see if somebody is interested in attending and can free up their schedule to do so. I think that would be important.

DR. FRANT: Okay, and the other role that --

CHAIRMAN CERQUEIRA: And then on March 15th, you said you would have a draft rule, a draft guidance document available, and will that be put on the Web? Will it be sent out to --

DR. FRANT: Both.

CHAIRMAN CERQUEIRA: -- the Committee members?

DR. FRANT: It will be published and distributed to all medical licensees through our distribution center. It will be on the Web, and it will be sent to the ACMUI Committee members as part of your Committee membership.

CHAIRMAN CERQUEIRA: Okay.

DR. FRANT: So it will be all three of those things.

CHAIRMAN CERQUEIRA: Niki, you had one?

MS. HOBSON: Yeah, I was wondering. Between now and March 15th, do you have plans to work with the professional societies that you alluded to earlier, that they have a lot to contribute if they have the time and willingness?

DR. FRANT: No, I think what we're trying to do is just take the document that we have, clean it up based on the comments that we've gotten recently, and put it out, and then at that point work with --

MS. HOBSON: Okay, but there will be involvement by the professional societies at some point?

DR. FRANT: Yes, and that's what these meetings in April are about and the planning meeting on March 14th is for how to engage that community.

CHAIRMAN CERQUEIRA: Just again one comment. And I feel kind of bad. We don't have a nuclear medicine representative on the Committee because the SNM ACNP really had the most comments, criticisms of the guidance document.

DR. FRANT: Right, but I think Chip has been calling some of those folks, and the Chairman

certainly has corresponded with them. So I think that they're aware of March 14th and will be part of the comment process.

CHAIRMAN CERQUEIRA: Again, I think it would be important to get it out to all of the professional societies.

DR. FRANT: Exactly.

CHAIRMAN CERQUEIRA: In the past, this Committee has in some ways been sort of a battleground between various interests from physician groups and everything, and I think we really should make the information available to all the stakeholders,

And sort of in terms of these dates, if people want to send -- now the meeting on March 14th, is that open to the public?

DR. FRANT: Yes, of course, it would be.

CHAIRMAN CERQUEIRA: Okay. Again, it would be important --

DR. FRANT: It would be a noticed meeting.

CHAIRMAN CERQUEIRA: Right.

DR. FRANT: And what I guess I want to insure, that we have a cadre of folks that are important to be part of the planning process, and then it will be noticed.

CHAIRMAN CERQUEIRA: Good. Again, I think

if you could send out information to the specific groups who have representation on the ACMUI, but to all other stakeholders and people who have sent comments, I think that would make certain that everybody with an interest knows about it and can organize sending people.

DR. FRANT: To some extent I'm relying on Chip Cameron because I think he has a long history with different groups.

CHAIRMAN CERQUEIRA: Okay. John, you wanted to?

MR. HICKEY: Yeah. Mr. Chairman, I just wanted to clarify, first of all, to repeat that the guidance document will be published for public comment, not as a final document.

CHAIRMAN CERQUEIRA: Sure.

DR. FRANT: In March.

MR. HICKEY: And that we will be going out for input and sending invitations to all stakeholders and organizations. It's not our intent that ACMUI will be the vehicle by which we communicate with other stakeholders. The ACMUI is free to do that, and we will solicit input from the ACMUI, but we are in no way saying that the ACMUI is the organization that's responsible for going to the other stakeholders and --

CHAIRMAN CERQUEIRA: Sure. No, and I'm not suggesting that, but I'm just saying that for all of the stakeholders, they need notice to send people.

MR. HICKEY: Yes.

CHAIRMAN CERQUEIRA: And March 14th is relatively close. It's three weeks away. So I think it's important to get it out.

And I realize that this is a draft, but you have gotten comments. The SNM ACNP was very specific in terms of the guidance documents, and so the closer the draft can be to a final the better off it will be for everybody.

So all right. Other questions or comments? Jeffrey.

DR. WILLIAMSON: Well, I think in preparing the draft, when I reviewed the document as it existed about a month ago, I guess, I didn't think enough effort was made to try and indicate the spectrum of possibilities that users could have in implementing. I was too focused on one set of model procedures.

You know, I think a lot could be done to ameliorate that by adding paragraphs here and there, indicating the areas where a lot of flexibility exists so that it's whoever reads that manual indicates --

realizes that this is just a possibility, and that other options can be implemented and the licensee won't be punished for doing it.

CHAIRMAN CERQUEIRA: I liked your comment about sort of a minimalist document which gives people a certain amount of responsibility. Obviously, you know, it's performance based, risk adjusted. I think they're very important, key words, and if taken to heart, I think it would certainly reduce the amount of information that's there for diagnostic and even for the therapeutic community as well.

DR. FRANT: But at the same time, I guess, I'm conscious of the fact that I've heard from many staff members, particularly license reviewers, that they're asked: is there a place I can go to --

CHAIRMAN CERQUEIRA: Right.

DR. FRANT: -- and find a model procedure that gives me an idea about what is expected?

And that, as I said, is a tension, and to the extent that we could have joint documents or that it could be produced by someone other than NRC as, you know, this is a recommended way to go. That would be fine, and we've done that in other areas.

In the meantime, there's a vacuum and something will fill that and perhaps we can take these

model procedures and have them someplace else that are available, but they're not seen as required even with a little r.

CHAIRMAN CERQUEIRA: I think the professional medical societies would certainly all give you their cooperation in an effort to get this done. The only point I would make is to try to get sort of a broad representation.

You know, for the reactors, you had a single entity, I guess, produce a document. I think --

DR. FRANT: You would think they are more monolithic than they are, but each utility has its own philosophy.

CHAIRMAN CERQUEIRA: Right, right. I think just to keep us on time, again, being cognizant of the flight schedules, I'd like to thank --

DR. FRANT: Okay. Well, I'm going to stay because I have a role in the next presentation. So --

CHAIRMAN CERQUEIRA: Okay, but again, I think it was an excellent presentation. I especially like the specifics with the dates, the time lines and everything else, and it would be very useful to the committee if we could get Angela to E-mail those out to us so that we can go back to our constituents.

DR. FRANT: Okay.

CHAIRMAN CERQUEIRA: Thank you, Susan.

Ralph.

MR. LIETO: Dr. Frant, just to clarify, the March meeting and its purpose, is it to get stakeholders there and how to best get the revised document addressed or is it to address how these public meetings are going to be conducted?

I'm still unsure as to what the March 14th meeting --

DR. FRANT: It's more about what the public meetings -- what role they can play in influencing the guidance document, you know, and who should be there and how we can best get comments and incorporate them into the final document. So it's a planning meeting for the meetings in April. Is that clear?

MR. LIETO: Thank you.

CHAIRMAN CERQUEIRA: Dr. Frant, you've done such a great job with time lines. I guess the one thing I'm still unclear on is that, you know, we saw the submission that the Commissioners sent to Representative Callahan, and have they heard back? When will they hear back? That's kind of a key question in this, isn't it?

DR. FRANT: I agree.

CHAIRMAN CERQUEIRA: The answer is?

DR. FRANT: The answer is that in the letter we sent to Congress, and I guess it's been stated enough times, and the Chairman, I believe, made some phone calls to key congressional representatives, to make it clear that the intent of the Commission was to publish the rule 30 days after the date it was sent to Congress.

So we hold our breath because if there's some strong sentiment among the legislators to tell us, no, you don't have permission to use the monies in your budget to implement Part 35 and you're not to publish it, that may happen. And that's what Marjorie, I think, was alluding to.

There's no guarantees except if you buy a washing machine from Sears, and -- sorry.

CHAIRMAN CERQUEIRA: Okay.

DR. FRANT: But, I mean, it's the truth. And so at the same time, I think that just my personal sense is that the Chairman and the Commissioners did some leg work and fully intend to publish it and believe that they won't have a legislative change, you know, with some legislation.

So I think the optimistic glass half full

view is that within 30 days of sending the report to Congress, we will send the Part 35 as it stands to the Federal Register to be published and to be effective six months after the date of publication.

We're working to that. You're assuming that.

CHAIRMAN CERQUEIRA: Right.

DR. FRANT: But it isn't there until it's there.

CHAIRMAN CERQUEIRA: That's great. That's very useful then.

All right. Well, so this section is now status of the NRC Web site in terms of security restrictions, and John Hickey is going to cover electronic forums; is that --

MR. HICKEY: Correct.

CHAIRMAN CERQUEIRA: And the Web site is?

MR. HICKEY: Dr. Rathbun is here to talk about the Web site.

DR. FRANT: Okay. Pat, before you start, I want -- Dr. Diamond, you made some comments yesterday about bad people using good stuff to do bad things, and you know, there's --

DR. DIAMOND: I like that. I like that.

(Laughter.)

DR. FRANT: So I've been working with FEMA, and John Hickey has been working on a lot of not for public discussion or not for public release information about things that could be done with radioactive material, not therapeutic and not diagnostic. And the issue is I know the advisory that went out to all of our materials licensees said that you should safeguard the material more so than you have in the past, and I think the suggestion in the advisory says something about looking at it as a controlled substance and some of the safeguards you have for controlled substances.

I have the sense that you're working on guidance to send out to medical licensees on what they can do to sort of implement that request of the advisories to look at more safeguarding of radioactive material when it's used in medical applications.

DR. DIAMOND: Not specifically. My general comments regarding bad people doing bad things with good materials was more of a general informative point that the societies are trying to go and just educate their constituent members as far as basic resources and procedures that are out there in case one of these events should happen.

DR. FRANT: Oh, okay. So this would be in

response to.

DR. DIAMOND: More of a response. I can tell you that in many, many radiation safety organizations or committees across the country there is, however, a formal move to safeguard these materials much more cautiously. For example, our institution, where the board scope holder really serves to oversight many, many smaller facilities, we've taken steps to take some programs where very, very little manual brachytherapy is done and go and consolidate those materials into a central location where obviously safekeeping and oversight is much better.

Perhaps I can ask a member of the audience. Nancy Daly is here. Nancy, do you happen to know offhand any more specifics with respect to if Dr. Frant's questions is actually being looked at in that committee?

MS. DALY: No.

MR. HICKEY: Step to the microphone and identify yourself.

MS. DALY: Nancy Daly from Astro.

Again, we're more specific to if it were to happen what would be the mechanism that would be put in place, and what resources could radiation

oncologists offer to the communities where it happens, and --

DR. DIAMOND: All right. Could I -- I'm sorry.

DR. FRANT: What I was going to say is, okay, so I misconstrued what you said because what I was going to offer is if we could play a role in having our safeguards group review things for you, we would be glad to facilitate that.

DR. DIAMOND: And I was going to say that I think that as you bring this up, this is an excellent point that would be welcomed.

DR. FRANT: Okay. Because we have, of course, a safeguards group that's been working with the intelligence community and with others about issues related to radiological dispersion devices, radiological emitting devices, REDs, RDDs, and of course, independently developed nuclear devices, which I think is not an issue --

DR. DIAMOND: Correct.

DR. FRANT: -- because it's fissile material, but the RDDs and the REDs are things that I guess there are medical use isotopes that could be involved.

DR. DIAMOND: I think we all recognize

just as you're alluding to that if a bad person wanted to do bad things with good materials, that going after hospital supplies or materials would be, unfortunately, a way to go, and therefore, we could certainly welcome that advice.

DR. FRANT: Well, I guess if as a community there's some work, then we could put you in touch with some of our safeguards people.

MS. DALY: Yeah, and we're also working with the American College of Radiology and the physics AAPM. So --

DR. FRANT: Okay.

CHAIRMAN CERQUEIRA: Dr. Nag had a comment.

DR. NAG: Dr. Cerqueira and Dr. Frant, at the last ACMUI meeting there was some discussion that if something bad were to happen, the ACMUI would probably be one of the first ones contacted, and much discussion about that. And there should be some formal mechanism how the ACMUI should behave should anything happen.

DR. FRANT: Well, we can talk about having some kind of a secure briefing.

DR. NAG: Right, and I think one of the things at the last meeting, that an action item was

that the NRC would come back to whether we will have some training session or at least some briefing session so that we can know how to react to the news media, how to react to the people nearby, and you know, how we can train the other people.

DR. FRANT: Well, we have some materials that we've prepared with many other federal agencies, including HHS and FEMA that are for federal government use. Let me see if that can be distributed. I'm not sure. It's official use only, but I'm not sure how other -- I'm learning about the different levels of protection. I know classified and nonclassified. There's a new one coming up that I guess Pat can talk about, which is the Office of Homeland Security is coming up with a homeland security sensitive designation, and that's something we're working through. That would be a new designation.

DR. NAG: At the last meeting we were talking about some official training and official briefing that the ACMUI should receive.

DR. FRANT: Okay. Well, I'm going to let John and Angela work that out.

CHAIRMAN CERQUEIRA: So do we want to make that an action item then?

PARTICIPANTS: Yes.

CHAIRMAN CERQUEIRA: To basically --

DR. NAG: It was made the last time. So I think we would just repeat the same thing.

CHAIRMAN CERQUEIRA: Again, for the transcribers, if you could somehow highlight this, it would be important.

DR. NAG: The **action item** would be that ACMUI members have a training session and/or a briefing for any untoward accident in nuclear --

DR. FRANT: Well, it would be potential --

DR. NAG: I don't want to use the wrong word.

DR. DIAMOND: Malevolent.

DR. FRANT: I can never pronounce that.

DR. DIAMOND: Malfeasant.

DR. FRANT: Right. You know, in Great Neck High they never taught me that. Anyway --

CHAIRMAN CERQUEIRA: All right. We should -- I really want to try to keep on schedule. So why don't we go on to this section, and maybe, Ms. Rathbun, if you could, we've got 15 minutes, John, to do this section.

MR. HICKEY: Yeah, that's fine.

DR. RATHBUN: It will be very short, not a problem.

Thank you very much.

This is my name tent. Well, that's all right. "Answers to the name of Pat frequently." Okay. All right.

As you probably know, after September 11th, in consultation with the Justice Department, the NRC did close down the public Web. Access to ADAMS was still available to those people who had already had access to ADAMS.

CHAIRMAN CERQUEIRA: I'm sorry. What's ADAMS?

DR. RATHBUN: All right. ADAMS is a document management system for the agency called ADAMS, and it's essentially where the NRC stores electronically all of its documents, and if you -- it's available to the public. You can just simply come in and look at whatever documents are in there, and theoretically it is the official record system of the NRC.

So you can see immediately there were some interesting paradoxes because we had the Web closed, but we had availability of ADAMS to people who had already had it.

So time passed, and Susan began to head a project whereby we were making decisions about what

should come back to the Web, when it's available, and what should be if not removed from ADAMS, at least significantly safeguarded.

Now, as you can imagine, this was a huge task. It was also carried out very rapidly because, you know, people were very, very concerned. It involved both the reactor side, as well as the NMSS side.

What did we really take down that could be of interest to you?

In our fact sheets, we had a fact sheet on the medical use of radioisotopes. The reviewer said drawings attention to the fact that some medical facilities have some very hot sources.

At that time, that document was taken and classified. Well, "classified" is the wrong word. And marked sensitive.

We also had another fact sheet on the biological effects of radiation, which the reviewers at that time, and you can see they were very cautious, said, "Contains language concerning cancer threat."

So the current decision on these things is to put the biological effects of radiation fact sheet back out onto the Web, but so far not the medical use of radioisotopes. So that's something that you may or

may not want to comment on, not necessarily here, but we're going to hold that back.

The ACMUI transcripts are public information, and they are available. IMNS Management prior to you actually reviewed that and felt there was no reason to pull that back. So unless I hear, you know, violent opposition here today, that will be going back on the Web.

NUREG 6642, the risk document which, you know, contains the detailed we feel kind of scenarios or how to make trouble, that was removed. It is still off the Web. No plans to go back.

Now, so that's where -- yes, sir.

MR. LIETO: So none of the NUREGs are available? Because it's my understanding --

DR. RATHBUN: No.

MR. LIETO: -- the RegGuides and the NUREGs are not available.

DR. RATHBUN: Well, let me go to that part.

At the same time that this was going on in response to closing the Web due to the terrorist activities, there was an activity going on to more or less straighten out the Web and come up with a new design.

What's happening now is documents are returning to the new Web, but with this sort of cloak of security. I don't know today if the NUREGs are back, but unless --

PARTICIPANT: They're not.

DR. RATHBUN: They're not. Okay. Unless they're marked "sensitive" in ADAMS you should be able to get them, but they are coming back.

MR. HICKEY: Excuse me. Another way to say that is if they were previously public, they will be put back on the Web public with a few exceptions --

DR. RATHBUN: Right.

MR. HICKEY: -- generally that won't affect medical licensees.

DR. RATHBUN: Yeah, I think the only one is that 6642, and if there were implications in any of the risk work, I know Lawrence Kokajko has spoken to you about the activities of the Risk Group, the results of that project are being withheld until we determine if there are risk scenarios that could simply lead the way to a terrorist.

Now, I mean, as you well know, this puts us in quite a balance between what people really need to do their business and what, in fact, might be used by bad people to do bad things with good material. So

what's happening?

Well, we're working on definitions and policies sort of very, very, very hard. I mean, there's a group of people whose major job is now to work on this and try to get as much information back out on the Web as we possibly can.

We are working on this both within NRC, but also with Homeland Security, and what Susan was referring to is called -- it's a new classification for information, and it's called sensitive homeland security information, which people are calling "sushi." So if you hear people speaking of "sushi," that's what they're talking about.

And Homeland Security's definitions currently are pretty general, but it's not at all clear to us exactly where they're going.

Un-huh?

DR. WILLIAMSON: I'm a little concerned at what you've just said. It seems to me --

DR. RATHBUN: I'm not surprised.

DR. WILLIAMSON: -- that it's totally ridiculous to take the medical use fact sheet off of the Web. You can go to any textbook on radiological sciences and learn that high intensity radiation sources are used for radiotherapy or for nuclear

medicine.

DR. RATHBUN: I totally agree with you.

DR. WILLIAMSON: And so I think a more realistic screening of the material needs to be made. I think it's appropriate to withhold details about the operational characteristics of specific sites, such as power plants that would perhaps aid in someone, you know, launching a specific attack or action.

DR. RATHBUN: Right, exactly.

DR. WILLIAMSON: But to withhold general material about the operation of the NRC, about the use of radioactive materials in general, and its activities, I mean, I think that's infringing upon your charge --

DR. RATHBUN: You're absolutely right.

DR. WILLIAMSON: -- as an open and public agency. So I --

DR. RATHBUN: In that one we totally agree with you, and there are about six fact sheets that at the time it seemed like -- you know, it seemed like a good idea at the time right after September 11th to pull everything that even, you know, had any hint.

There's a whole pile of them, about seven, that I suspect will go back just next week. So, you know, I totally agree with you. If we erred in the

beginning, I think we erred on the side of probably overly cautious, and I think that what you see from the Commission is a move now to be much more realistic.

DR. FRANT: The Commission has directed us to go back and make sure that we're not doing exactly as you're suggesting. At the same time, the Sealed Source and Device Registry, for instance, we've made that password protected, and only if you have a password can you used the Sealed Source and Device Registry, on the assumption that there are detailed drawings that can give somebody an idea on how a device could be dismantled or whatever.

It may be that unless you know where the device is it wouldn't matter if you knew what to do with it, and you would only get that if you put one and one together, one being the Sealed Source and Device Registry with its detailed documents and then found licensees' names and who is using that device and a map of where they were.

On the other hand, it's clear from some of the intelligence that we get that there are people who are willing to do al of that leg work. So you want to make it a little more difficult.

And we did have many, many evidences of

hits coming from all over the world to different parts of the NRC Web site, and it may be things that are in a textbook, but the Web is very accessible, and so there was a very conservative decision made right after 9/11 that we'll just put the Web down and wait until we figure out what we can put back up.

And as Pat said, we're doing two things at the same time, which sometimes confuses the issue, which is putting things back up, but putting it back up on our new Web format. So it's taking a little longer to get some of the NUREGs back up, but they are slated to go back up, and I don't know exactly what the date is, but they've been in waves.

And as with the rest of what we do here, the reactor stuff went back up stuff, and the medical stuff will follow.

CHAIRMAN CERQUEIRA: Richard, did you have a question?

DR. VETTER: Yeah. The information in the public document room is also readily accessible.

DR. FRANT: Absolutely.

DR. VETTER: And I'm not sure how that -- sure, it's easier to go on a computer, and you can do that --

DR. FRANT: From anywhere in the world.

DR. VETTER: -- from anywhere in the world, but the public document room is also there. My question relates to information that at least in the past has been available in the public document room, and that is: is there information either in the license literature or in enforcement literature that would reveal the location of radioactive materials at a medical center?

DR. FRANT: I'm sure there is, and I'm sure in enforcement documentation this is something we have been looking at. There are discussions of vulnerabilities that need to be corrected, and that's also problematic. Because if it hasn't been corrected yet, then it says you have a problem.

I was leading the team that did the review at NIH when they had the P-32 contamination, you know, and we had documents on what the security issues were.

DR. VETTER: Yeah, personally I would view that as more problematic than having NUREGs and so forth out on the Web.

DR. FRANT: Yeah, and I think you're exactly right, and it's one of Pat's issues, is to come up with guidance that helps us make those decisions so that we don't make it on each document, but we make it on categories of documents.

Right now --

DR. RATHBUN: If possible, if possible.

DR. FRANT: Right now the things are in the public document room partially because you have to go there. You have to sign in. We know who's looking at the stuff, and that's part of what we're looking at, is who has access, not only --

DR. WILLIAMSON: Maybe that is a better approach to your problem, is to try to define -- make an application system for people to get passwords so that they could have access to a broader scope of information.

Rather than trying to classify every single document, you could screen people who have access and supply passwords to users from the medical center who need to get into this stuff.

DR. FRANT: Yeah, well, we have to be careful --

CHAIRMAN CERQUEIRA: Just in terms of --

DR. FRANT: -- that we don't use criteria that --

CHAIRMAN CERQUEIRA: Right. In terms of the Committee, I need to give John some time for his forms. What specific questions do you have for the Committee relative to this?

DR. RATHBUN: Honestly, I didn't have any questions. I just wanted --

CHAIRMAN CERQUEIRA: Just information.

DR. RATHBUN: -- to inform you, and I'd love to hear from Dr. Lieto.

MR. LIETO: First of all, I use ADAMS fairly frequently because you can use it to confirm training and experience, credentials of new users at your facility as to whether they were actually licensed or not and what licenses they were on.

Regarding Dick's question, yes, there are floor plans and locations of where stuff is because basically a license application is full copied in its entirety. So that information is there.

My concern is that there's a lot of information as an RSO and a physicist that you want access to the regs., you know, current versions of the regs., which are sometimes very difficult to get, and I --

DR. FRANT: Those should be up there. Those should be up now.

MR. LIETO: But lots of times though --

DR. FRANT: We'll check.

MR. LIETO: Part of the issue is like if you want a copy of Part 35, you've got to go through

and copy each section. There are not entire parts that you can download for distribution to users and for training purposes, and so forth. The same thing with like Part 20, Part 19.

DR. WILLIAMSON: Oh, it's terrible.

MR. LIETO: Those types of things. So it's very difficult, and I would think that that would be very helpful.

Another comment regarding what you're planning to do with the NUREG revision. To me there's going to be a lot of people who can't get to these meetings and so forth, and I would see that the Web site is going to be really critical because of the time frame for people to make comments and suggestions and want to get input to the NRC.

So I know that when the original Part 35 revision when out there was a site, and I think it was at Lawrence Livermore, but I could be wrong, where people could have dialogue on the issues, and it was monitored, I think, by the NRC staff for comment.

I don't know how beneficial it was to the staff or not, but there's got to be, I think, that Web site mechanism for communication on this Part 35 revision that I think is really important.

And I know I'm being looked at over here

about the clock and so forth, but, hey, I've got the mic.

DR. FRANT: You bet.

MR. LIETO: So I think the Web site is a very --

CHAIRMAN CERQUEIRA: I could cut you off.

MR. LIETO: -- is very important.

DR. FRANT: Well, I think we intend to use that. I don't see Roger, but the last I heard, the staff planned to have that Web site up.

MR. LIETO: Now, the other issue is regarding ADAMS. Because of the way of accessing ADAMS, if you have firewalls, it's very, very difficult to access ADAMS, especially for like large centers and so forth. In fact, the only way I can do it is via a modem. I can't do it via our hospital network, which is a very slow process.

And so if you've got a sizable document, I mean, you've got to basically kind of do this overnight. So, you know, to look at get sizable NUREGs and things like that to download, it is not easy. In fact, it's very difficult to do it because you've got to do it via modem.

DR. FRANT: Yeah. We'll pass that on to our CIO folks who have done the Web redesign. I think

they tried to address that. This has been a complaint by many, many groups. We've been accused of using the Web as a way to disenfranchise people who didn't have computers and elitists and all of that.

CHAIRMAN CERQUEIRA: I suggest that we take a break. Let John cut into Don Cool's time a little bit, and if people have --

DR. RATHBUN: That's fine.

CHAIRMAN CERQUEIRA: No, but if people have specific questions for Dr. Frant and Rathbun, just ask them now. Okay?

DR. RATHBUN: Yeah.

DR. FRANT: We'll be here.

CHAIRMAN CERQUEIRA: Thank you very much.

(Whereupon, the foregoing matter went off the record at 10:06 a.m. and went back on the record at 10:22 a.m.)

CHAIRMAN CERQUEIRA: I was talking to John during the break, and we have every intent of being completed by three o'clock. A lot of the items after the three o'clock break were really sort of dealt with to some extent.

I'd also like to mention that, you know, I think the Committee meets. Most of us, this is not our main line of work, and for some of these this was

very informative, but it would be very useful if we had some questions that they wanted to ask us specifically, and if they're going to sort of update us on something, having the material sent to us ahead of time would allow us to view it on the plane, if nothing else, so that we could provide some useful input into the NRC on these items.

So, again, I think some of these updating the Committee on factual items, we should get the material ahead of time, and if there are specific questions that they have for the Committee, I think these, again, should be clearly stated. Otherwise we just have a nice dialogue and we get a little bit of information and we exchange cards, but we could be much more useful and productive if we knew ahead of time what they're going to present and what information they want from us specifically.

MR. HICKEY: Yes, we agree with that, but let me just point out a couple of considerations. One is this was in response to a request from the Committee to place this on the agenda. It wasn't that the staff --

CHAIRMAN CERQUEIRA: Right.

MR. HICKEY: -- had questions they wanted to bring to the ACMUI.

The other is we agree that we need to provide you with material advance, but an example in this particular case is where it involves security considerations we have to be careful what we put down on paper.

CHAIRMAN CERQUEIRA: Sure.

MR. HICKEY: And was you heard, this is a dynamic situation where it's unclear what's being release to the public and what's not.

CHAIRMAN CERQUEIRA: That's understood, and we are certainly aware of those factors, but again, to get more business done, it's important to have it.

All right. Well, the next item then is going to be John with the electronic forms.

MR. HICKEY: Yes. Dr. Cool is in a meeting that should have ended by now. So we're expecting him momentarily, and Mr. Lohaus is in a meeting also, but we expect him to be here on time.

With respect to the electronic forms, and I think some of Ralph Lieto's remarks were a good introduction to this, we would like for the Web site to be more user friendly and more useful, and so we will be putting electronic forms, in general, up ont he Web more, and in particular in the medical area

where there are forms that are useful, such as an application form or a reporting form.

We're going to have that as part of the medical tool kits, Web tool kits, so to speak, that that's another resource that instead of having to get the forms through the mail in hard copy or Xerox them out of something, you can download them and fill them out, and perhaps even submit them electronically.

So that is one thing we're working on, and we're also looking at other user friendliness issues.

Ralph pointed out one that's come up before, the issue of our regulations. If you're reading them the way that they are on the Web, if you're just reading them on the Web it's fine, but if you want to download the whole document, you can't just click Part 20 download. You've got to click 20.201, 20.203 and download each one of those individually.

So that's an agency-wide issue, not just a medical issue, but that's something else we'll have to work on.

CHAIRMAN CERQUEIRA: Good. So that's it on forms.

MR. HICKEY: That's it. I'll take any questions.

CHAIRMAN CERQUEIRA: And Dr. Cool is still not here.

MR. HICKEY: Unfortunately. We just called up there. He's going to come down as soon as he gets out of his other meeting.

DR. VETTER: Can I just make one comment?

CHAIRMAN CERQUEIRA: Yes, please.

DR. VETTER: The public document room does provide -- I don't know if that's -- it's some electronic connection of the public -- not public document room.

The Government Printing Office. You can download entire chapters from that. At least, unless something happened since September, I have done that in the past.

MR. HICKEY: From the Code of Federal Regulations.

DR. VETTER: Yes.

MR. HICKEY: Yes, but that's not user friendly for you to have to go -- you know, we'd like to have it you go to the NRC Web site; you go to the medical area; and it's all right there. That's our goal.

DR. VETTER: Can you link?

MR. HICKEY: We can, but I don't know if

that's the best way to do it because that involves, you know, relying on another server and going out of the system and coming back into the system.

CHAIRMAN CERQUEIRA: Yes. Now for the sake of time, it looks like the next two speakers are not going to be here. Bob Ayers is here. John and I had talked that there's some sort of stakeholders. I guess is there -- is there a reason we couldn't move that up on the agenda now?

DR. AYERS: I don't have my slides here.

CHAIRMAN CERQUEIRA: Okay. So I guess we can't do that.

DR. AYERS: I can go up and get them, but it would take a few minutes.

CHAIRMAN CERQUEIRA: Well, maybe you should, and what about na update on new IVB devices?

MR. HICKEY: I can go ahead and talk about intravascular brachytherapy.

CHAIRMAN CERQUEIRA: Yeah.

MR. HICKEY: Before you do that, would you like to talk about the three o'clock, to see if we could --

CHAIRMAN CERQUEIRA: We could touch --

MR. HICKEY: To the extent that the three o'clock items need further discussion, we could close

those out.

DR. WILLIAMSON: Or we could decide the next meeting date.

CHAIRMAN CERQUEIRA: Okay.

DR. WILLIAMSON: There are some other administrative things we could prepare.

CHAIRMAN CERQUEIRA: All right. So the distribution of ACMUI meetings.

MR. HICKEY: Minutes.

CHAIRMAN CERQUEIRA: Minutes. I think we've agreed that it's, you know, two weeks before the time of the meeting itself, if not sooner, is idea, so people can review it if there are issues.

And I'm certainly willing to look at the items as they come to me. I will not commit to going through the transcript of the entire meeting. I think we've simplified it, you know, with Dr. Diamond's suggestion to try to come up with specific agenda items. So --

MR. HICKEY: To be clear, the minutes will be clear on what the action items and resolutions were and what the staff's response was to those as a separate document.

CHAIRMAN CERQUEIRA: So, again, we've got a policy, and we just have to enforce it.

Ralph?

MR. LIETO: I just had a question. Where are the transcripts of the minutes or -- excuse me -- of the meetings? They're in ADAMS only? Is that where they're at or are those supposed to get distributed to the members?

MR. HICKEY: Well, let me ask Angela. I'm not sure you want them distributed, but go ahead. Speak into the mic.

CHAIRMAN CERQUEIRA: Trust me. You don't. It's huge.

MR. LIETO: Well, I was just thinking of --

MR. HICKEY: Well, let Angela answer the first questions.

MS. WILLIAMSON: The transcript is placed into ADAMS after Dr. Cerqueira certifies it, and that can typically take from the time that we get the transcript, that can typically take about 30 days.

Yes, Dr. Williamson.

DR. WILLIAMSON: Is it possible we can have access provided to ADAMS for the members of the Committee and then E-mail given to us to direct us or to inform us when the transcript and minutes are available, and then we could go look at them on line?

MS. WILLIAMSON: That's a routine announcement that's made in the Federal Register notice about when the transcript is available. So you're asking for us to notify you precisely when it's available?

DR. WILLIAMSON: Right, because we don't all read the Federal Register every day.

MS. WILLIAMSON: Right, but it is in your --

MR. HICKEY: We can notify you by E-mail of the availability and how to access it. Anybody can access ADAMS. You don't have to be given access to ADAMS. Any member of the public --

DR. WILLIAMSON: Okay, but if you can tell us when and where --

MR. HICKEY: And how, yes.

DR. WILLIAMSON: -- it's on the Web, and how, that would be really nice because we're not going to read the Federal Register every day to find out.

MR. HICKEY: Go ahead.

MR. LIETO: I was going to say because usually documents have sort of a weird ID number, if I'm not mistaken, in ADAMS. So you know, if we even have that number so that we can go in and find it.

CHAIRMAN CERQUEIRA: Okay. Dr. Cool is

here, and while he's getting set up, an update of the ACMUI bylaws. What did we change? Were there any changes or is this --

MR. HICKEY: It was pointed out that there needs to be an update with respect to the terms. The length of terms of members has been changed, but the bylaws haven't been updated. So we will update that and any other administrative changes.

And I would suggest that we contact the Committee by E-mail with the revision, and then for the next meeting the approval of the change would just be a formality. It would have already been reviewed.

But the main concern was they did not reflect the correct length of terms. They just had not been updated.

CHAIRMAN CERQUEIRA: Okay. I have to admit I haven't read them for a while, but they're here now.

Is this a revision that -- okay.

MR. HICKEY: Can you explain what's been handed out, Angela?

MS. WILLIAMSON: To save time, I handed out the proposed change to the bylaws so that when we get to the point in the agenda when we talk about updating the bylaws you can read what the proposed

change is, and you have the current version of the bylaws already in your briefing binders.

So that's all that that is.

CHAIRMAN CERQUEIRA: So the only thing that's changed is the term of an appointment to the Committee is three years and the Commission has determined that no member may serve more than two consecutive terms, or a total of six years.

MS. WILLIAMSON: Right. The total amount of time hasn't changed. It's just that the terms have been lengthened.

CHAIRMAN CERQUEIRA: Okay.

MS. WILLIAMSON: That's the only difference.

CHAIRMAN CERQUEIRA: Does anybody have any concerns about that, questions or disagreement with those changes?

MR. LIETO: No, I think we've just got to vote on it.

CHAIRMAN CERQUEIRA: Yeah. Do I hear a motion to approve?

MR. LIETO: I make a motion to amend the bylaws, Section 3.1, to reflect the Committee appointment term length as documented here.

DR. NAG: One question.

CHAIRMAN CERQUEIRA: Yes.

DR. NAG: How would those who are appointed for two years and now we have a three year -- I mean the new appointee, no problem. What happens to the old appointees?

MS. WILLIAMSON: Can I answer that? It's simply an administrative change so that the appointment process --

MR. HICKEY: No, the question is: is there anybody on the Committee now that was appointed for two years?

DR. NAG: Yes.

CHAIRMAN CERQUEIRA: I think most of us.

DR. NAG: All.

MS. WAGNER SCHWARZ: All of us.

CHAIRMAN CERQUEIRA: Was it for three years?

DR. WILLIAMSON: The bylaws are out of step with the current process.

MS. McBURNEY: With the process.

CHAIRMAN CERQUEIRA: So it sounds like, you know, the process was changed, but the bylaws weren't.

MR. HICKEY: Correct.

CHAIRMAN CERQUEIRA: I have to -- okay.

All right. So that's been clarified.

MR. LIETO: Second Ralph's motion.

CHAIRMAN CERQUEIRA: Second Ralph's motion. Any discussion?

(No response.)

CHAIRMAN CERQUEIRA: All the vote. All in favor?

(Chorus of ayes.)

CHAIRMAN CERQUEIRA: Opposed? Abstentions?

(No response.)

CHAIRMAN CERQUEIRA: Okay. So this has been passed, and we've dealt with that.

Dr. Cool, I apologize for taking some of your time, but we'll give it to you if you need it.

DR. COOL: Thank you, Dr. Cerqueira.

And let me welcome you here. With the number of the other things going on in the agency I haven't had the time I would have liked to have had to be with you on the large variety of subjects today. This may, in fact, not necessarily need as much time as may have been on the agenda. So I may, in fact, be able to help you just a little bit.

On the other hand, this is an area which is a little bit different from that which the

Committee typically has an opportunity to get a view of because I wanted to spend a few minutes and let the Committee have a little bit of information about some of the activities that are going on internationally because there is a great deal of activity going on outside of the United States, outside of this particular set of activities that we have here in the Nuclear Regulatory Commission.

And both because it is of general interest because of the interactions that we and the states and various professional societies may be engaging on in another one of our lives, as well as the potential implications that this may have long term for some of the activities or interactions that we may have, and because I believe it poses a new opportunity for us to at least consider ways to influence activities on a broader scale, and so for those variety of reasons, I wanted to give you a little bit of background information of some of the things that are going on and some of the recent discussions that have taken place.

The particular event which tripped my request to spend a few minutes was an International Atomic Energy Agency Technical Committee meeting which took place about two and a half weeks ago, and it was

titled the "Development of an Action Plan for Radiological Protection of Patients."

Now, that might seem like a very strange title for someone from the Nuclear Regulatory Commission to then be headed overseas on, but, in fact, under that title lies the current set of IAEA, International Atomic Energy Agency, activities related to the practice of medicine and radiation.

IAEA, as the states have here in the United States, has a view for all of the different kinds of uses of radiation in medicine. This is everything from the esclorays (phonetic) and the fluoroscopy to the biopartic (phonetic) materials to the PET, to the entire gamut of activity. So it goes well beyond NRC's particular jurisdiction.

And they have had in place for almost as long as the agency has been in place a series of activities that they've been looking at to try and support their member states in the safe use of radiation and radioactive materials.

The International Atomic Energy Agency is a U.N. agency, and so their member states constitute in the broadest terms the membership of the United Nations. In more specific terms, there are a set of member states of IAEA, somewhat of a subset, but it's

still some 150 or so different countries, and so they face a rather interesting challenge of everything from things like the United States and Great Britain, France, the various folks in the European Union, and others who have rather developed and refined programs, longstanding sets of regulations, practices, and activities and focuses, to folks in some of the smaller countries, some of the newly independent states in a variety of places where the first and foremost question is: is there any sort of regulatory infrastructure and information? Does anyone know what they actually have and what they're actually doing in using the radioactive materials not only in medicine, but in all of the various attributes, a lot of the industrial sources, radiography and other things?

But medicine tends to be the area where they are more likely to actually have large sources in some of these under developed or just developing member states as a result of teletherapy units or other things. A physician, a physicist, some combination of folks returning to their country, having been educated here or in Europe, and taking with them sources and equipment in order to set of practices, and that has over the course of time, of course, gotten people into trouble in various and

sundry forms both in terms of the securing and control of the material -- witness, for example, the Guyana event for now more than ten years where a teletherapy unit was no longer being used, was more or less abandoned. Some thieves came in and thought this would be wonderful scrap metal, got into the source, and saw, oh, what cool stuff. This cesium powder glows in the dark, and several people died, and they made a horrendous mess of a large number of acres there in Guyana, to similar sorts of things where teletherapy heads, for example, in Thailand here a couple of years ago, three of them picked up by scrap brokers. Again, they didn't know what they had. There was no ongoing accountability and control, and there were a number of individuals who got very severe exposures to rather serious consequences as a result of actually attempting medical treatment. Witness, for example, the most recent couple of cases in Costa Rica and Panama, for example, where there have been rather severe consequences, a number of individuals actually dying as a result of not being aware that a treatment planning system output was not what they had thought they were putting in. The system didn't respond the way they thought it was going to.

So there's a whole set of issues that are

going on. The International Atomic Energy Agency and its Board of Governors in a general conference back several years ago, the Board of Governors challenged the IAEA Secretariat to convene an international conference to try and examine the issues and lay out some recommendations for how to move forward in the area.

That resulted in a conference that was held in Malagra, Spain back a bit over a year ago. Commissioner Diaz from here; Dr. Fred Metler actually chaired the conference, University of Mexico. A number of other individuals from various places within the United States attended the conference. There were over 800 participants.

That resulted in a series of recommendations coming out of the conference, documented in the proceedings which are publicly available. It's a book about yea thick, a couple inches thick. A wide variety; contains all of the text of the talks and the dialogue sessions.

The general conference in September of last year asked the IAEA Secretariat, the staff to then move to the next step, which in typical international activities is to more formulated specific action plan, which the IAEA could then engage

specific actions on over some period of time.

That's the short history that got to the meeting that was held the end of January, the first few days of February this year, taking the results of that conference and taking a look at the current IAEA programs and what things could be done and what things should be done by whom. Because the IAEA is only one of a large number of organizations that have international roles.

The conference and this technical committee was attended by representatives of the World Health Organization, WHO, Pan American Health Organization, PAHO, a whole series of various international professional societies, the International Organization of Medical Physics, International Radiation Protection Association, International Society of Radiation Oncology, International Society of Radiographers and Radiological Technologists, International Society of Radiology.

That gives you a flavor, a wide variety of these, all of whom have various activities going on to one extent or another, trying to look at improving the delivery of medical care internationally.

The discussions during the week and the

focus of the action plan being developed. I have a very drafty draft that I brought back, which they were going to go work on, polishing and adding to some things, picks up on the primary mechanisms that the IAEA can utilize to influence member states, which is coordinating research where that may be appropriate to gain a better knowledge of the things to do; promoting education and training, which was, in fact, one of the primary focuses of this activity; providing assistance to member states, which is something that the IAEA does through both technical assistance activities, some peer review activities, a variety of things that they do with developing member states; fostering information exchange, such as the conference and other activities; and in some cases actually specifically rendering some services to some of the member states, where they will actually come in and perform certain functions for a period of time.

The outgrowth of that is a whole series of suggestions for actions to be taken, some of them over the next year, some of them a little bit longer time frame.

Once I have a better version of this draft or if that's not forthcoming from the IAEA within the next couple of weeks, I will circulate this particular

version around. I will get you a copy recognizing what it is, that it is a draft.

The process in IAEA is then to have this proposed action plan approved by the Board of Governors, and what would then transpire is over the next year, couple of years, the IAEA in coordination and cooperation with some of the other international agencies, particularly folks like WHO and PAHO, would be looking to try and implement some of these activities.

Many of the things in this action plan are not actually things which the Nuclear Regulatory Commission in and of itself would likely play any specific role in. They are nevertheless good things, trying to foster education and training, trying to look at what are good practices in terms of some of the protocols that they can give to folks to be able to utilize to improve information, how to foster getting the right kind of information into the hands of the people who need it.

There are some things related to some of IAEA's activities in standards and guidance. There the planning activity looks very much like the directionality that we have here with NRC and in the United States to move towards performance based sort

of activity, to be trying to look at the relative risks associated with it.

And at this point in IAEA, their primary focus is things like the fluoroscopy, some of the interventional radiology, some of the very high dose rate procedures where their view of risk is perhaps a number of years behind some of the thinking and views that ours would be.

They will have some efforts to revise some of the guidance documents that have been used in working with member states, their so-called model program.

To give you a quick side bar related to that, their model program is an effort with now some 58 member states where they have gone in and started from, in essence, scratch. There's no regulatory structure; there's no regulatory authority. There's no understanding of the sources and uses and activities.

Through a series of steps working to build a basic infrastructure, a basic understanding, a basic capturing of registration or licensing of the kinds of sources that are to gradually move to a point where there is a basic system of control, inspection, and licensing.

They've developed associated with that some documents that a member state could use, not necessarily unlike model procedures. If someone doesn't have the capability to work on developing their own, they can use these .

They've committed to doing some revisions related to those, to in a number of cases make them less prescriptive and to provide some flexibility. There were a number of observations that a bunch of the places here couldn't do everything that was in the list of some of those best practice documents that existed out there, and how could you possibly expect someone in Ghana or some other very small developing place to ever be able to implement that sort of program?

So I bring this to your attention not that it requires specific action by the part of the Committee, but to make you aware that there is a whole other sphere of activities, and that I would expect a number of things that the IAEA and the WHO and others to be doing and moving forward with this might well be things which you as individual Committee members and some of the societies and groups that you represent would want to become involved in.

Ruth is shaking her head up and down. I

think the states and both OAS and particularly CRCPD will want to get into a number of these because they are actually more closely aligned with some of the work that IAEA will be doing.

We, in fact, thought that Paul Schmitt might be able to attend this, and when Paul was not able to, that's why we defaulted back on a relatively short time frame. We made the decision that this was the kind of meeting developing actions where the U.S. simply couldn't afford not to have some representation or to make sure that they didn't move in a direction which would get to be prescriptive and might have ramifications coming back for our particular programs.

So there are going to be a lot of ongoing opportunities. If this action plan is anything like some of the other action plans that the International Atomic Energy Agency has, it will assume a life of its own for at least some period of time.

It will likely go through some updates and revisions over the next two years as things start to be accomplished and they start to look to what additional things might be done. I would expect that they would want to have a follow-up international conference to take a look at progress that's being made.

No such thing has been scheduled, but I would guess by 2004 or so they might be looking to have another conference to assess the activities.

And with that I would be glad to entertain questions or you might want to go with this other area of activities.

Dr. Nag.

DR. NAG: I've been involved with the IAEA consulting for the last about eight years, and I have been involved in the developing section on the research program, and one of the things they have done is taking developing countries and pairing them with a number of developed countries.

And we formulate what are the protocols that can be used in developing countries to treat cancers, and we develop the guidelines and we sort of supervise the treatment there.

I think that's a very good exchange. We give some of the brain power, and they have different problems and different kinds of basic populations, and you know, we help develop those.

We also do guidelines for things like guidelines for developing countries, for HDR. Many places are now using HDR, but they don't know how to use them, and we had to develop guidelines for them.

And we have also done publications to standardize brachytherapy in developing countries. So those are things that have been ongoing now for the last eight years.

DR. COOL: Yes, and this action plan will, I think, continue those, maybe give them a little bit higher hat in terms of some visibility and focus and trying to move forward. A number of the things related to education, training, the best practices, guidelines, a number of those things are the key components that relate to this action plan and trying to get those sorts of things available for use.

There was a recognition in the conference, and I think it's also reflected in what Dr. Nag just said, for some of these folks, I think it's fair to say they don't have clue or they have very little clue. They're out there on their own.

And that which we take for granted in terms of being able to interact with peers, understand where best practices are going doesn't exist. They don't have an ongoing access to that kind of information.

So the first step and one of the themes of this whole thing was can we arrange a system which will enable anyone to make progress from where they

are, and some of the tools which now we might not want to have at a very forceful level are, in fact, necessary to have perhaps a higher degree of force within a country that's just starting in order to be able to leverage the initial steps of the process.

CHAIRMAN CERQUEIRA: Don, I saw the minutes of the meeting and then some subsequent drafted minutes, and PET got singled out quite a bit. There was quit an emphasis on PET.

But if you look at sort of penetration and usage, it's relatively small. Did you get some idea as to why PET was sort of identified as an area of concern or need to monitor?

DR. COOL: It was viewed as something that's emerging. At the risk of sounding just a little bit silly, it was also a pet of several of the folks who were there.

(Laughter.)

DR. COOL: As with all meetings of this type, the individual specialties of some of the representatives and their particular concerns tended to show up in some of the discussions and activities.

So one of the things that I have found interesting in a variety of international forums that I have had the opportunity to participate in is the

need to actually sit back and literally change your hat, to take a view with regard to where things need to go and the things that are necessary in an international context, which may be different from the local contexts.

And the degree to which the committee of the whole was doing that varied a bit across the week, as you might expect. So there was some discussions of all sorts of modalities.

There was a great deal of focus on medical physicists and the need to get more medical physicists, and quite a bit of actually side bar discussion on the fact that a number of the legislation and other activities don't allow a medical physicist to be recognized.

And so none of the regulatory authorities believe that a medical physicist is necessary, and they just draw a little arrow, and somewhere they're over here, and how to get a recognition of the importance of some of the components, again, that we more or less take for granted as being important to a team, which for various legal or other reasons haven't got that same degree of recognition some other places.

CHAIRMAN CERQUEIRA: Jeffrey.

DR. WILLIAMSON: Yeah, well, it really is

challenging. I, too, have been involved in the IAEA activities, and they're really trying to not just create a regulatory system, but they're trying to leverage and create basic quality assurance standards --

DR. COOL: Precisely.

DR. WILLIAMSON: -- and standards of practice.

And you know, in this country standards of practice arose independently and the regulatory system came later as, you know, it was felt necessary to have oversight as a consequence of various instances. So they really have a different challenge.

DR. COOL: Yeah, and just to reinforce that point, something that I was attempting to allude to, but you've made it a little bit more clear. A lot of the standards and practices, standards of practice and guidelines which we have at a level of the users in the professional societies in which the NRC and others deliberately stay out of so that you can continue to move your best practices, in the international context at this point need a much higher level.

They're actually talking about them in terms of the regulator and others in order to get the

initial step of even getting anything in place. It's a bit jarring, except for the recognition of the situations which they're dealing with.

And part of what I was attempting to do was to make sure that in the action plan and in the activities that the descriptions and the flexibility was such that that couldn't in some way inadvertently come back to haunt us. And I think it's a challenge for all of us as we participate in some of the various forums and consultants and otherwise just to continue to promote that message and help everyone make progress.

CHAIRMAN CERQUEIRA: Other questions for Dr. Cool?

(No response.)

CHAIRMAN CERQUEIRA: Well, if not, thank you for sharing your information with us.

DR. COOL: I appreciate the opportunity, and as I said, I do hope to circulate some version of this. If I don't have a final version within a few days, I'm going to put out the report with the version that I got, and at that point we will make sure that individual members of the Committees have a copy of that so that you can see where it is in its drafty state, unapproved by the Board and heaven only knows.

CHAIRMAN CERQUEIRA: Thank you.

Now, is --

MR. HICKEY: I'm not sure if Mr. Lohaus is going to be here on time, but Dr. Ayers is ready to proceed in the meantime in any case.

CHAIRMAN CERQUEIRA: Good. Now, is anyone aware of any groups that were coming to this meeting specifically to hear the information on the Board recognition who may be disadvantaged by having to switch the time?

PARTICIPANT: Bill Malagan (phonetic) was going to be here about 11:15.

CHAIRMAN CERQUEIRA: Yeah. I think he can get enough feedback.

DR. AYERS: Good morning. I managed to get my slides down.

Just to preface my presentation, my presentation and what I'm going to talk about, the Boards, is all predicated on the current draft new Part 35, not any dealing with any of the discussions which I think were useful, and you're heading in the proper directions on modifying the rule language, but for what I have to work with now is what we have for the current rule language.

CHAIRMAN CERQUEIRA: And, Bob, I think

realistically that's what we're going to deal with because all that we've talked about with these other changes would require a rulemaking, and that's going to take some time.

DR. AYERS: Yeah.

CHAIRMAN CERQUEIRA: Is that --

DR. AYERS: Well, if I can have the next slide, the Boards, just to review, that have applied in one form or another for recognition are the nuclear medicine, pharmaceutical specialties, medical physics, health physics, Board of Radiology, and in the next slide several others.

If I can have the next slide, please.

The Board of Nuclear Medicine Radiology, Science and Nuclear Medicine, and the Certification Board of Nuclear Cardiology.

Next slide.

The American Board of Medical Physics applied for recognition under 3551(a), which is authorize medical physicist, and we're all aware of the problems with the full recognition is not possible under the Board system because of the specific requirements for training in each of the modalities.

But it certainly does look like partial recognition may be possible to work with the Board,

and what one or more of the components does the Board have sufficient training in that could grant recognition?

And the recognized physicist could come in as has been discussed previously with specific training and experience, say, on the gamma knife for a teletherapy unit or a vendor's training on the remote after loader and add those authorizations.

CHAIRMAN CERQUEIRA: Bob, just how would that be done? How would partial recognition be done?

DR. AYERS: Well, we're in the process of preparing letters to the Board, and we ask -- and the letter, the draft letter in this case says, "Well, okay. Come back and tell us which one of these components does your current Board recognition process encompass."

And if they can show us that it encompasses one or two or more, we should be able to work towards granting the recognition for 35, 400 manual brachytherapy plus teletherapy, whatever the combination might be.

DR. WILLIAMSON: So when you say partial recognition you mean four more modalities.

DR. AYERS: For modality based recognition, yes.

DR. WILLIAMSON: Modality based recognition. Well.

CHAIRMAN CERQUEIRA: Jeffrey, does that answer some of the issues that we've brought up and how could --

DR. WILLIAMSON: Not really. I mean, I'm not sure that there is -- is there a requirement for an authorized medical physicist in 35.400 at all, except for decay of Strontium-90?

DR. AYERS: That's one of the requirements.

DR. WILLIAMSON: That's the only requirement, right?

DR. AYERS: I'd have to review it in a little more detail to answer your question.

DR. WILLIAMSON: But I don't believe that they will be able to comply with any of those three.

DR. AYERS: Okay. Well, I mean, it's an option if they are, and the letter is starting the process of going back and forth to find out where we are.

DR. WILLIAMSON: I, frankly, think a more fruitful approach or an additional approach you might consider is to give them credit for if someone has this ABMP certification, that that automatically takes

care of the various years of experience and is evidence for having an appropriate degree.

DR. AYERS: Well, that's what you're talking about in the rulemaking space.

DR. WILLIAMSON: No, I was talking about in guidance space. You could use it as a criterion for determining who meets the basic training and experience requirements and, you know, hours of experience per se, and having the degree. You could accept that.

DR. AYERS: Well, that's another form of partial recognition, yeah. We can --

DR. WILLIAMSON: That's a form of partial recognition.

DR. AYERS: Yeah, we could say four plus --

DR. WILLIAMSON: I believe you could implement in guidance space to preserve some recognition of the Board's certification process, and then you would have to ask on top of this. You'd have to have reasonable criteria for supplementary training in these three modalities.

DR. AYERS: Yeah, that's a form of the partial recognition. The partial recognition imbeds in it none of the specific modalities, but it says it

meets all of the training experience requirements, except the specific device.

DR. WILLIAMSON: Yes.

DR. AYERS: The material which -- and that's another four. This is what the process that we can work on. That's one direction we can go.

CHAIRMAN CERQUEIRA: Dr. Nag.

DR. NAG: Yeah. One important thing, in your impartial recognition, you have to give the credit that when you have gone through a Board, you may not have specifically done remote after load (phonetic), that you're not getting your credit for after load, but you got the 500 hours separately for the --

DR. AYERS: Yeah, that's what we were talking about, yeah. That's a possibility, yeah. The process is on hold now to start the information exchange between us and the Board until the rule's status is clarified.

CHAIRMAN CERQUEIRA: Bob, I kind of hate to have brought you up here and now our other speaker is here. I think this is important and we should come back to it and see if it could help us out of our dilemma to some extent, but, John, do you think we should switch gears here?

MR. HICKEY: Yeah. Mr. Lohaus is here. So I think we should proceed.

DR. AYERS: And I just started.

MR. HICKEY: And Bob can come back to his presentation later.

DR. AYERS: Right. I just started. I can pick it up again after lunch.

CHAIRMAN CERQUEIRA: A few more opportunities to skewer him. Okay.

DR. AYERS: No problem.

(Laughter.)

CHAIRMAN CERQUEIRA: Thanks for your tolerance of the Committee here, Bob.

MR. HICKEY: I'd like to introduce Mr. Paul Lohaus, the Director of the Office of State and Tribal Program, and Mr. James Myers from the same office.

MR. LOHAUS: Good morning.

CHAIRMAN CERQUEIRA: Welcome.

MR. LOHAUS: I welcome the opportunity to meet with you.

Let me recognize Jim Myers. I understand you wanted to talk about the National Materials Program and current status and where we're going. Jim was co-chair for the National Materials Program

working group, along with Kathy Allen, who at that time was chair for the Organization of Agreement States.

But maybe by way of background just a couple of introductory remarks. Part of the genesis for the National Materials Program really comes out of the growth in the number of agreement states. If you look at the number of states that were projected, we're at 32 today. We're projected to go to 35 by FY 2004, and the proportion of licensees that the agreement states had responsibility for, really they're going to have about 75 percent of the total number of licensees in the country.

And in recognition of that, what the Commission did is directed the establishment of working group to look at options in terms of how should we function in the future relative to our program, and that's where the term for the National Materials Program comes from, relative to both NRC and the agreement states, given this continued shift in the program with the states having the larger proportion of licensees.

And the process that was used was the working group was set up of NRC and agreement state staff, and they worked for about a year and a half and

developed a report which was provided to the Commission in May of last year, and we brought with us copies of that Commission paper.

You may have copies. If not, we brought copies. So if you'd like you can take a copy with you.

CHAIRMAN CERQUEIRA: Yeah, it would be good to give it out to the Commission.

MR. LOHAUS: And basically what the working group did is examined a number of options, and they range from some rather what I would term drastic changes in the program whereby you would shift the program back to NRC having complete responsibility for regulatory jurisdiction over all licensees in all states to an option where all states would take over that authority, with the exception of a few categories of licensees where at least by current law NRC would need to maintain regulatory jurisdiction.

For example, federal facilities where jurisdiction resides with the federal government, as opposed to the state government.

There were a number of middle options, and the option that the working group settled on and is really their recommendation is what's called an alliance option, and basically the alliance option is

a program structure that's very reflective of the current evolution of the program today.

In other words, what it reflects is a sharing of regulatory responsibilities among the states and NRC. There would be a process of using centers of expertise, for example; a process of using working groups, coalitions of technical staff among the agreement states and NRC to help develop regulatory products that are needed to support the program, and those products could then be used by either NRC or the agreement states.

It sort of pushed the envelope on this concept, but at the same time, that option is reflective of current evolution of the program where there's a lot of activity and a lot of sharing in utilization of expertise within both the states and within NRC staff to address common problems, to identify solutions to those problems, and help, you know, basically bring the best expertise and the best talent to addressing those problems.

There's a couple of questions or big issues when you look at this that we're going to be examining in some follow-on work, and one of these questions is: will the states be able to take on increased responsibility and provide the resources

that would be necessary under this alliance type concept, you know, if we were to move in that direction, and produce a product on schedule that could be used by the states and also by NRC?

And at the same time there's sort of a question on the other side, and that is, you know, will NRC be able to use a product that's developed by the states and fold that into its regulatory program without a tremendous amount of additional staff effort. In other words, there would be some savings and reduction in the FTE loading that NRC would experience in terms of development of the regulatory infrastructure and supporting products that it would need for its program.

So what we have under preparation today is a second paper for consideration by the Commission, which would identify what I would term some pilot programs to provide further opportunity for the NRC and the state staff to work together, to help provide some of the demonstrations that are, I think, necessary to help support the concepts and the thinking that's reflected in the working group report and their concept of the alliance program.

And some of these pilots could be very simple. For example, developing a new guidance

document or taking an existing guidance document and maintaining that document up to date, in other words, insuring that it meets current practice, reflects current state of the art, et cetera.

Other cases it may be that there may be a rule area that's identified that's in need of attention. That may be an item that could be addressed through a working group and a rule package prepared that could be used both by the States and by NRC to address that particular rule area.

But we're looking at a number of different --

DR. WILLIAMSON: I'm sorry. Could you make clear what alliance is as a regulatory structure and how it differs from the current overall regulatory structure with respect to the domain of NRC, whether it's NARM or byproduct material? It's not clear at all what you're saying.

MR. LOHAUS: Well, I think some of the points you mentioned are some of the issues that would have to be addressed as a part of this program. Presently, as you're aware, NRC does not have regulatory jurisdiction over NARM materials.

The states do. This is an area that the Commission did ask the staff to prepare some

proposals, which are with the Commission for consideration. But this is an issue that, you know, when I spoke earlier saying the alliance sort of represents the current evolution of the program, but there are additional parts to that that would need to be addressed in the future.

And this could certainly be one of the areas in terms of whether NRC should assert and maintain regulatory jurisdiction over NARM as a part of the alliance process for those states where we have regulatory jurisdiction or whether we would continue with the current situation. But I think those are some of the issues.

What I might do is maybe ask Jim if he could maybe talk through in more detail some of the thing.

CHAIRMAN CERQUEIRA: People are getting kind of anxious and raising their hands, and I kind of hate to defer questions.

MR. LOHAUS: Okay.

CHAIRMAN CERQUEIRA: So maybe we could let people ask questions to the specific things that you've identified so far.

MR. LOHAUS: Sure.

CHAIRMAN CERQUEIRA: I mean, how many of

you are aware of this ongoing process?

(Show of hands.)

CHAIRMAN CERQUEIRA: So really it was only Ruth, and I think the rest of us are a little bit --

DR. NAG: In the dark.

CHAIRMAN CERQUEIRA: -- in the dark about this, and I think it would be important here --

MR. HICKEY: Excuse me. Mr. Lieto had requested a presentation on this topic.

CHAIRMAN CERQUEIRA: Which I think is very important. I mean, Ralph is asking all of the right questions, you know. Just as a new member, I think he's -- and I think this is very important and really impacts on a lot of things we've done with the Part 35 revision.

But why don't we take questions now and then we could -- so Dr. Nag.

DR. NAG: Yeah. How would the role of the ACMUI play in this National Materials Program? We are giving our input to the NRC. How would that impact the National Materials Program?

And the second thing is how would this National Materials Program help to insure that there is some similarity between the different states. For example, you know, the rule in one state may be quite

different from the rule in another state, and doctors go from one state to the other, and you know, that makes some problems.

MR. LOHAUS: I think both of the items you raise are very good questions and very good issues and are things that would need to be addressed and explored as a part of future work.

Let me back up and make a very clear statement. There is no preferred option that has been identified at this point in time. The report of the working group was provided to the Commission for consideration, and we are preparing the second paper I mentioned, but I want to make a point that, quote, the alliance option which was the preferred option recommended by the working group, that the agency and the Commission has made no decision yet relative to a preferred option.

But in terms of the Advisory Committee, I think you raise a good point. The Advisory Committee would certainly continue, in my judgment, in my view, to advise the Commission as it has in the past, but if we were to head more towards an alliance structure, there may be additional advisory considerations that the Committee could play in terms of the broader National Materials Program alliance structure.

CHAIRMAN CERQUEIRA: So it hasn't really been considered.

I guess one question I would ask you is it seems a little bit self-serving that the NRC hires the states to come up with a plan and basically the conclusion is make no change at all.

If we go back to the Institute of Medicine review, which the NRC commissioned and which was released in what, '95 and '96, they clearly made the point that it should all go to the states, which I guess if we look at page 1 in the very back, description of options and assumptions for resource estimates, it would really be the independent state option.

Why was that not, you know -- I mean, based on that report, they felt that that was the best option, to basically minimize the federal regulations and put it at the state level, which 95 percent of all the radiation that's used, ionizing radiation, is state regulated.

MR. LOHAUS: What I might do in this case is defer to Jim as co-chair for the working group. I mean, they went through a lot of discussions, a lot of deliberations, obtained a lot of feedback in, I think, their report, and their recommendation in that report

is reflective of the views of the working group, which was both NRC and agreement state staff, as well as the various input that they received.

CHAIRMAN CERQUEIRA: What about the stakeholders, the physicians? Were they involved in any way or was their input sought?

MR. LOHAUS: Jim?

MR. MYERS: Yes. Dr. Cerqueira, good to see you again.

CHAIRMAN CERQUEIRA: Yes.

MR. MYERS: It's been a while.

Let me just kind of paint a little bit of what the vision of this is, with the understanding that the Commission has not made a decision about alliance structure or any of the other structures that were proposed.

The working group wrestled with, and I think quite openly came to the table and sat down and said, "Well, okay. What's wrong and what do we need to do to fix it, given the scope of the SECY paper that the Commission asked us to look at some things?"

The issue is, and I think that initially almost everybody came to the table and said, "Well, heck, you know. Maybe this whole thing just needs to be thrown out and we'll start again."

But I think through the process of discussions, of laying out some very good objectives for the working group to achieve, to try to do it in a rational fashion, what we really came up with is that what we have today is a pretty good system. It's not perfect, and there's maybe no expectation that it would ever be perfect, but there's certainly some things that we can do that would in the context of what the Commission asked us to do, would be to improve the process and basically to seek more input and advice and perhaps even using products that are developed by the states to do, you know, certain things in medical or it could be GLs or whatever, to use those kinds of things and incorporating them more into a national program than they are now.

And maybe what comes to mind is that -- I don't know. Since everybody is here and didn't see this, but the FDA approved a new drug called Zevulin today. That's just out. That uses Indium-111 and it used Yittrium-90, and it's basically a therapy drug.

But if we used this as an example, you know, you can envision today that there would be like 33 different regulatory agencies that would approach how to license or regulate this particular therapy drug, and what we would say is that maybe we need to

have, for lack of better terms, more of the working group approach, where we get somebody who has some expertise in this maybe -- I'll say the State of Texas, for example, maybe the State of Georgia or Rhode Island, whoever has worked on this -- and some NRC folks together to come up with a template or a concept of how to regulate this and what would be required.

That would then be subsumed by the national program, meaning all of those organizations. So we don't have to reinvent it 33 times. We would take something that's good, modify it for the individual use of the state or the NRC slightly, and then be able to use it right away.

And that was the idea of trying to get more input from the states and do more of that. Clearly, the working group recognized that perhaps it's not totally efficient to drop NRC out entirely, but clearly the role seems to be diminishing, and you can look at the different scenarios down here.

Even if you had no other NRC licenses except those in the military and the VA and some others, it's still a tremendous cost to the agency, but it doesn't solve the questions that the Commission asked us to look at, is what do we do now that we

don't have the expertise. How do we regulate medical if we don't have any hospitals and we don't have that emerging technology like Zevulin or stuff to deal with?

So that's kind of how it came about, and the report is kind of lengthy, but there is an executive summary to it, and this report here that we just handed out, I think, also kind of characterizes a lot of that thinking.

CHAIRMAN CERQUEIRA: Jeff?

DR. WILLIAMSON: Yeah, well, it sounds a lot like the Institute of Medicine report in terms of the layout of your options, and certainly that was a highly controversial report and probably one reason it was discarded by the Commission and not followed, was that the regulated community fragmented in terms of what option they supported.

This Committee extensively reviewed that report and looked at the options, and you know, the 50 independent state regulatory associations, that was rejected by this Committee out of concern that there would be absolutely no uniformity in any of the basic regulatory structures or training and experience requirements and so on that would really hamper the practice of medicine.

So, you know, I think that would remain a concern probably of this group if we came up with it again, is how can uniformity be preserved, given this tendency for the states to become agreement states.

MR. MYERS: If I can respond to that, on page 2 of the handout that we did, about the middle of the page, there's some bullets there. These are essentially kind of the evaluation or they are actually the evaluation criteria that the working group used, obviously, protecting health and safety, optimizing resources of federal, state, professional, and industrial organizations, at the same time, we need to account for individual needs and abilities of agencies, promoting consensus, promoting an exchange of information, and you know, harmonizing regulatory approaches.

These were all factors that we looked at, and this is the way it breaks out if you use a decision matrix and use these as part of your evaluation criteria. You end up with the concept of the alliance as being the one that is the most favorable in terms of achieving those some six or seven objectives.

And I think that addresses your issue about fragmentation and other things. Clearly there

has to be a partnership, I think is what the working group was saying; is that somehow it has to come together so that you do talk, do share information, and you have good information exchange and a number of other things, and we're to have a harmonious program nationally.

MR. LOHAUS: You know, the question of national harmony, I mean, we use the term compatibility. That's in our statutes, but that's an issue that has been with the agreement state program from its inception and will continue to be with us in the future, and I think that there was focus within the working group, and it's reflected in the criteria that Jim mentioned on this question, that you need to maintain a degree of flexibility so that individual programs can address legislative direction and other aspects.

But at the same time, there needs to be a degree of consistency and harmony so that there is not disruption, there's not major differences between individual states and those under NRC regulatory jurisdiction.

And we've tried to address this in the Commission's adequacy and compatibility policy and our implementing procedures, but it will continue to be an

issue. There will not be complete uniformity and agreement among all the states from my experience in the program. You will see differences, but my goal, and I think the goal of this agency is to insure that there is a level of harmony and coherence and consistency within the programs across the nation, which we accomplish through our compatibility part of the program.

The two aspects are the adequacy component and the compatibility component, and what I've seen on the part of some of the working groups is that in sharing in the process of developing the regulatory product, irregardless of what it is, but there's greater agreement on the product and greater agreement on wanting to move forward and implement that product in a consistent manner.

And that's part of the concept, I think, that is reflected in the alliance concept, is that using a working group process, you would hopefully end up with a product where there is agreement and there isn't wide variation in terms of how that product would be implemented.

So there is good consistency, and the regulated community has assurance that it's going to be predictable, consistent, and understandable. And

I think that's a goal not only of our program, but I think of the states as well.

But at the same time, from my experience you will see some differences, and there's not going to be complete consensus in all cases. And to me it's a strength that we see in the program because given some of the differences in view and given different approaches, that considering those and reflecting those actually results in a better product that's going to serve all of us in a better way.

And that's one of the strengths that I see in that program.

CHAIRMAN CERQUEIRA: Dr. Nag.

DR. NAG: Yeah. What would the policy be of the Materials Program? Would it have authority over the states and be, you know, more like a coordinating body among the various groups?

MR. LOHAUS: Are you speaking with respect to NRC or the alliance itself?

DR. NAG: The alliance.

MR. LOHAUS: See, the NRC, over oversight responsibility in our oversight program would not change. When you look at the alliance option, there's a very clear role that NRC would continue with the integrated materials performance evaluation program,

the current program we use for review of both the state and our regional materials programs.

So NRC would continue with its oversight program, and that responsibility would not change. So, you know, if there are cases where there are both issues with respect to the adequacy in a program and issues with respect to compatibility, we would be able to address those through our review program.

DR. NAG: Right, but is the National Materials Program a separate entity, a separate body? If it is, what is the authority between the National Materials Program, the NRC, and the different states?

I'm somewhat confused. I might be --

MR. LOHAUS: Again, you raise to me a very good issue with respect to the alliance, and I'm going to ask Jim to also comment here, but part of what you do come away with when you do think about this is you think of the alliance as a separate entity, and it may not be a wholly identified separate entity as much as a structure or process structure in which the NRC and the states will function in the future.

And, on one hand, you could say, well, we're going to have an alliance organization, and I've had difficulty in my mind trying to understand if there was, quote, an alliance organization. What is

that? What's it made up of? What does it do? Who's it responsible for, et cetera?

But, on the other hand, I can also look at it from the standpoint that it's a process relating to how NRC and the states will interact and function in the future, and as such it's not a clearly identifiable entity.

But, Jim, I know you all wrestled with this, and maybe you can help add some perspective on this.

CHAIRMAN CERQUEIRA: How is it different than what we're doing now, I guess, is one question that can be asked.

Jim?

MR. TERAO: Yeah, this is a real, real tough thing to kind of characterize, but it is more of a process than a physical entity. That's for sure. It's a process that's made up of the different organizations, and that would include ACMUI. It would include other standard setting organizations. They are kind of plug and play. As they need to come in and interface into the alliance process or into a rulemaking process, we would expect that that would happen.

I think what we see is what's different

about this is the fact that as the current system exists, there are conflicts and there are stresses and there are demands that are placed upon all of the states and on NRC that are many times conflicting, and they consume a lot of resources, either, you know, money or it could be energy, a lot of different things.

And through the process of like the conference where we have some committees that work and those are well established, the OAS was another organization the Commission asked us to integrate into this working group; in looking at the whole thing, what we saw was that, well, the process itself that we use today really isn't terrible. It just isn't, but there are some conflicts with it, and there certainly seems to be a better way of doing business.

And how to do that would be perhaps to come together. This is in theoretical space, is that at some national meeting or it could even be a virtual meeting as far as we were concerned; is that you would establish some national priorities, maybe getting some regulatory guidance out, and how to regulate Zevulin, for example would be a national priority at this point in time.

And we would bring together what we call

centers of expertise to work on that issue, and then they would, again, share that with the alliance, and for everybody to use versus individuals going out and doing the work, which seemed to be counterproductive.

CHAIRMAN CERQUEIRA: I think we all understand the concept and the potential for doing it, but I guess just in terms of being pragmatic, I'm just not quite certain what new entity or structure you're going to create that would create this harmony, compatibility.

We've had multiple discussions here amongst the group just in terms of training and experience requirements and how the difficulties we're going to have once those get implemented and this three year lag period.

But I think Ruth has had her hand up, Niki, and then Jeff always has a question. So --

MS. McBURNEY: Just coming from a stark regulatory perspective, the way that I see this occurring is it's going to have a greater role and responsibility for the state, for the agreement states in that the states are going to have to put forth more resources.

An example of that was that there were two state people on the Part 35 working group, and they

had to commit a lot of time away from their regular jobs to do that, but the states are willing to do that and also a greater role in setting the priorities for rulemaking.

For example, several years ago the State of Texas decided that the training of industrial radiographers was a key priority, and we went ahead and set up a certification program. And several years later then the Nuclear Regulatory Commission adopted similar regulations. So it is now a national program.

So the way I see this National Materials Program working is that the states, along with the Nuclear Regulatory Commission, would set some national priorities for rules and procedures and so forth, and then establish the working groups to work together to come up with that so that everybody is not trying to reinvent the wheel, that we're not having to commit a lot of resources just to do it in our own state, that it can be more of a national program.

CHAIRMAN CERQUEIRA: Again, I think the concept is commendable, but just the structure is a little bit unclear.

Maybe, Niki, you were having a comment?

MS. HOBSON: Well, that's precisely my question. Could you draw us an organization chart and

show how this thing is going to work?

DR. WILLIAMSON: Let me just express my question, which is relevant. Could you describe the potential statutory changes that would have to be made to implement the alliance? Maybe that would help us understand.

MR. LOHAUS: Okay. I'll answer the questions in the order.

CHAIRMAN CERQUEIRA: In two minutes.

MR. LOHAUS: One is I don't think we can provide an organization chart for the, quote, National Materials Program or for the recommended alliance option at this point in time because I don't think they're sufficiently clearly defined.

But what we need is a recognition and a sensitivity, and it's reflected in your comments and your concerns in the issues you're raising. And you are raising very good questions and very good issues, that as we move forward, there needs to be a recognition that NRC shouldered and really, you know, NRC licensees, given our fee system, shouldered, and the lion's share of the regulatory cost, if I can use that term, for maintaining the infrastructure of supporting regulations and standards.

And from an equity and fairness

standpoint, if you look at this from the standpoint of proportion of licensees, a question is: given that the states are regulating about 70 to 75 percent of the total licensees, should they play a greater role and responsibility in the resource costs for maintaining that infrastructure?

And along with that goes the responsibility to maintain consistency and coherence, and that's the issue that the Commission framed for the working group, and that's the issue that is still there, that we're continuing to wrestle with, and it's a National Materials Program issue.

And you can look at different approaches on how we might want to address that. You can look at legislative issues. For example, one legislative issue could very well be with respect to whether NRC should assert broader regulatory jurisdiction over naturally occurring in accelerator produced materials, for example, or whether it should be limited to all accelerator produce materials or just those that are used in medical applications.

But I think, Jim, you may want to comment here.

I think the sense of the working group was that there were probably only two areas where

legislation might be required, and that really depended on where you saw the National Materials Program headed.

One related to the regulatory jurisdiction over norm, and the second related to the question of whether jurisdiction over federal facilities, which is sort of a reserved federal authority, whether there should be some consideration of either changing that or providing a mechanism where the states could pick up --

CHAIRMAN CERQUEIRA: So those are the two areas, but maybe --

MR. LOHAUS: Jim, did you --

CHAIRMAN CERQUEIRA: I want to try to wrap this up a little bit, maybe get a few questions from the Committee, and then see if the Committee is going to recommend some action on this.

Ralph, I want to thank you for bringing this to our attention.

MR. LIETO: Well, you know, everybody is trying to get a handle on, you know, physically what this is, and I don't know if this would be an appropriate analogy, and I would ask this to Jim.

Would this be sort of a concept that would be similar to CRCPD except you've got a federal? It's

sort of a federal type of a situation with the Conference of --

CHAIRMAN CERQUEIRA: CRCPD?

MR. LIETO: CRCPD, excuse me. And --

CHAIRMAN CERQUEIRA: No, no, no. What does it --

MR. LIETO: Conference of Radiation Control Program Directors.

DR. NAG: What do they do?

MR. LIETO: Well, that's sort of a national group of all the state radiation control program directors that meet. I'm going to say it's more a professional group rather than a regulatory group, but they come out with national recommendations of state regulations, and so forth.

And it sounds like this is sort of analogous to that, except one of the partners in this group is the federal agency, the NRC. And would that be an appropriate analogy, taking into account that every analogy has its weaknesses, but would that be some way so that the Committee could get a handle on what this working group is intended to try to develop?

MR. MYERS: I think it's what we were envisioning as something that's Conference-like. Okay? And the difference is that Conference has, for

good reasons, has its hands in a lot of different things, and it's a very complex organization. What I think has to happen with it is that the concept would have to be broadened somewhat so that you get more of a national regulatory perspective, again, involving all of the federal players, whether it's FDA, NRC and others that have an interest in radiation protection, to bring them into this kind of a partnership or alliance concept basically to kind of set out national priorities and then to follow up on the accomplishment of those tasks associated with the priorities.

We didn't envision that we would create another NRC-like structure of some 3,000 people or so to kind of oversee all of that, but it would be basically made up of perhaps parties who had special expertise. It could be volunteers on the part of the states or other NRC employees to work on that at the direction of their organizations, to kind of ride herd on that process at least initially.

CHAIRMAN CERQUEIRA: I guess, you know, part of the discomfort that I'm sort of sensing from the Committee is that, you know, these are all very nice concepts, abstract, organizational structures, but we don't see enough of the framework on how to best structure it.

And I guess, you know, I'd sort of like to find out from the Committee. I mean, is this something that we should have been involved in? Is this something that we should be involved in in the future?

And certainly as a user, I guess the question I would ask is how is this going to make my life any different? Is it going to relieve all of this regulatory burden that I experience down at Georgetown every day?

If it does, I'm all for it. But if it doesn't, you know, big government is great, but if it's not going to help me, I'm not so sure.

So what's the sense of the Committee? Should we have been involved?

MR. LIETO: Well, one reason I brought this up is because it talked about stakeholder input.

CHAIRMAN CERQUEIRA: Right.

MR. LIETO: And it wasn't clear to me who the stakeholders were, and it appears now it was just the states.

CHAIRMAN CERQUEIRA: And the NRC.

DR. NAG: And the NRC.

PARTICIPANTS: No.

MR. LIETO: Well, I mean, they were not --

MS. WAGNER SCHWARZ: But the users are not?

MR. LOHAUS: I'd like to maybe separately have Jim respond to the opportunity for stakeholder input because there was a lot of opportunity.

CHAIRMAN CERQUEIRA: Sure. Can you describe that perhaps, Jim?

MR. LOHAUS: Please, yes.

MR. MYERS: Yes. We are very concerned about stakeholder input, and everything we did was totally public. It was all announced. It was all there.

CHAIRMAN CERQUEIRA: Yet the Committee didn't know about it, and we are representing professional medical societies.

MR. MYERS: I would say that, you know, we made sure that things were Internet available constantly. We had a stakeholders meeting specifically in Arlington, Texas in January of 2001.

CHAIRMAN CERQUEIRA: And who attended from the medical community?

MR. MYERS: I don't have the list here, but I can provide that to --

CHAIRMAN CERQUEIRA: Any organizations?

MR. MYERS: Oh, yes.

DR. NAG: Who are the stakeholders? You are talking about stakeholders. Who are the stakeholders?

MR. MYERS: At that particular meeting, and I'm sorry. I just didn't bring the notes on the meeting, but basically we invited folks from Health Physics Society. There was a gentleman from Texas who was with the Texas Health Physics Society. There was others.

We even got people in low level waste issues, you know. So that was quite a broad based thing.

MS. McBURNEY: I thought somebody was there from the Society of Nuclear Medicine.

MR. MYERS: And we had some folks from the Society of Nuclear Medicine and others there. Regrettable --

CHAIRMAN CERQUEIRA: The therapeutic community?

MR. LOHAUS: I believe ACR may have been represented.

MR. MYERS: Yeah, ACR was there.

MS. WAGNER SCHWARZ: And ASTRO.

MR. MYERS: And ASTRO as well.

CHAIRMAN CERQUEIRA: I guess I'm just not

tuned in. I mean, Dr. Diamond, were you aware?

DR. DIAMOND: No one at ASTRO let me know about it.

MR. LOHAUS: One thing. You know, being sensitive to your point, Dr. Cerqueira, one thing we can do in the future is meet with you at your regularly scheduled meetings or periodically and give you an update on where we are.

Again, another point maybe to try and put this in perspective for you in terms of timing, I don't see this happening immediately. This is going to be a long process.

CHAIRMAN CERQUEIRA: No. Part 35, we've been involved in what, Jeffrey? Fifteen?

DR. WILLIAMSON: Five years, six years.

CHAIRMAN CERQUEIRA: Yeah, and so I think, again, this is the reason we're all here, is that we represent stakeholders in the medical use, and we certainly would like to find out about changes that are going to affect this and would like to have input.

And perhaps that was provided, but certainly the people at the table who were fairly involved were unaware of it.

Maybe it was the fault of the societies for failing to give us the information, and I don't

think we disagree with some of these approaches, but I think I've learned to be a little bit more pragmatic about these things, and I think that would be helpful.

What's the sense of the Committee? Is this something we should be involved in and what role?

MR. LIETO: Can I? I just want to expand about the stakeholder issue.

CHAIRMAN CERQUEIRA: Yeah.

MR. LIETO: And when I found out about this. I don't mean to portray this negatively, but one of the things I wanted to bring to the Committee, because it seemed to me to indicate this is a direction where the NRC is going, which as an Advisory Committee obviously we want to be at least sensitive to maybe some significant changes in where the Commission plans on taking the regulation of radioactive materials.

So that was one reason that I think we need to be aware of because I think this alliance concept kind of -- it's much different than what I think any of us had thought NRC would be going in terms of the future.

And the other thing that came out at least of this article on the summary of the working group was that it pretty much said that the NRC needs to

seek authority to regulate NARM material, and that it seemed to be sort of a linchpin in order to make this alliance concept to go forth.

Now, maybe that's a strong term, "linchpin," but it seemed like it was very, very critical to making this work with the states. I mean, I'm definitely in favor of it personally, but I think, again, it was to make the Committee aware of where what's going on with the Commission, that maybe we're not quite aware of on the medical side, especially in light of PET.

You know, Sally was bringing up yesterday, you know, it's really important that we need to have some consistency in the regulation of radioactive materials both, I think, on the NARM and the byproducts side.

MR. MYERS: If I could just make a quick comment in there, the working group did not, and in fact, the way the report is written, it's pretty clear we did not say that the agency had to seek that authority to regulate NARM materials and then to go to alliance.

Actually you could go through the alliance process and seek the regulation. It's just that if the agency would seek that and seek to regulate it, we

believe that you would have a more uniform program because it would begin to kind of pull things together that are kind of untidy out there from a regulatory standpoint.

And as you know, NRC does not regulate that stuff right now, and that's an issue.

CHAIRMAN CERQUEIRA: Yeah, that's obviously an issue that's been present all along.

I'd like to try to wrap this up because rather than an hour and a half for lunch, I'd like to give us an hour, and we'd reconvene at quarter to one.

But, Ralph, did that address any other comments?

Dr. Nag had one last.

DR. NAG: Yeah. As far as funding and who is footing the bill for the extra bureaucracy? And is it going to be from the licensee again? You know, we made separate funding for the agreements, state licensing, and then the NRC, and then a different program.

MR. MYERS: I would say that as envisioned by the working group and absent the decision by the Commission as to what option that they want to choose, we did not see that there would be any additional cost in doing this because it's part of kind of

rechanneling some of the resources that are already out there and making it more efficient versus -- in other words, I wouldn't envision you would get a bill from the alliance for their services for the next year.

CHAIRMAN CERQUEIRA: Not directly perhaps, but --

MR. MYERS: But it would be somehow folded into existing processes and as the states do today. I mean, they provide resource and so forth, and that's not really --

CHAIRMAN CERQUEIRA: Yeah. If the state or the federal government are doing it, it's better than the stakeholders.

Sally, one last comment, and then I want the Committee to give me some direction on where we should go.

MS. WAGNER SCHWARZ: I actually do have a question just about whether the NRC has actually made progress or made steps to actually contact states to find out those interested in giving over state regulated materials to the NRC. Have they actually begun discussing this with the states?

I did see something that was sent to the State of Missouri. This is why I'm curious, and I

wasn't aware that it was a formal effort, but that something was sent and asking about the interest of having the NRC take over regulation of NARM. And I'm wondering if that was done to all non-agreement states.

MR. LOHAUS: There were two things -- I'm sorry. Go ahead, Ruth.

MS. McBURNEY: There have been resolutions passed at the Organization of Agreement States meeting in I believe the Conference of Radiation Control Program Directors encouraging this legislation.

MR. LOHAUS: That's correct, and there were two things that were done. One is the Chair of the Organization of Agreement States did do a I'll use the term "informal survey" of the states, and when we were developing the paper for the Commission in response to their asking for some feedback from staff on this issue, we did work with the Conference of Radiation Control Program Directors to help identify whether there were strong views among the different states one way or the other.

So we had some sense of where the states are when we reported back to the Commission. So that is the genesis, I think, of this.

MS. WAGNER SCHWARZ: Were they favorable,

the majority?

MR. LOHAUS: Yes, they were, yes.

CHAIRMAN CERQUEIRA: All right. Jeff, maybe you could ask your question afterwards because we should break.

DR. WILLIAMSON: I just wanted to make a comment.

CHAIRMAN CERQUEIRA: All right. One comment.

DR. WILLIAMSON: My comment is I think I'm rather concerned and alarmed at the thought of NRC expanding its jurisdiction over additional materials because it was not too long ago when NRC regulations destroyed the economic viability of certain treatment modalities.

And so for me personally, it would take a lot of --

CHAIRMAN CERQUEIRA: Yeah, that's -- that's --

DR. WILLIAMSON: -- convincing before I would find that acceptable.

I think if the problem is paying for the regulatory infrastructure that NRC provides for byproduct materials, perhaps you should go back to Congress and ask for a different funding mechanism so

that it's paid for out of the general revenues rather than penalizing the 18 non-agreement state licensees.

MR. LOHAUS: That's certainly an option, and I believe that's -- Jim, correct me if I'm wrong -- that's recognized within the working group report.

CHAIRMAN CERQUEIRA: Right. Now that's good.

Now, what are the wishes of the Committee? I mean, I certainly got the sense that people feel that this is an important development and there should be more involvement, input from the Committee. Is that the general consensus? I mean, anybody would disagree?

DR. NAG: I would support that.

CHAIRMAN CERQUEIRA: And how do we do that, John and Paul, Jim? I mean --

MR. LOHAUS: One thing --

CHAIRMAN CERQUEIRA: -- we haven't been asked, you know, to come to the dance, but is there a dance card? Can we sign up?

MR. LOHAUS: I mean, I guess one thing that I can do is provide information to the Committee, you know, for example, as we're doing today. Give you a briefing and --

CHAIRMAN CERQUEIRA: That would be a good start, and just, you know, even a full --

MR. LOHAUS: -- keep you up to date.

CHAIRMAN CERQUEIRA: Yeah.

MR. LOHAUS: And if there's areas that you see are of concern or interest and you want to report out on those areas, it gives you an opportunity to do that early and have an opportunity to influence the outcome and considerations.

CHAIRMAN CERQUEIRA: That would be a good start, and I think just sort of a list of the stakeholders who attended these meetings. Again, the fact that a lot of us weren't aware of it, I mean, I would just like to see if there was representation from the cardiology community, from the radiation oncology community. I think that would be important.

MR. LOHAUS: We could provide that to you, sure.

CHAIRMAN CERQUEIRA: How can the Committee get more involved in this?

DR. NAG: May I suggest --

CHAIRMAN CERQUEIRA: Sure.

DR. NAG: -- that you examine either by an observer or if you want to nominate someone else. Someone from ACMUI, whether an examiner or someone

else, be part of that working group or at least be an observer in the working group.

MR. LOHAUS: The working group is sunsetted. It completed its product. So the working group is basically sunsetted. It no longer exists. The product is completed, and as I said, what we're doing now is working on a follow-on paper to address the --

CHAIRMAN CERQUEIRA: But is there a final document that's gone to the Commission?

MR. LOHAUS: Yes, there is. We can provide that to the Committee.

CHAIRMAN CERQUEIRA: Well, but the recommendations weren't that clear, you know, in just the cursory time that I've had to look at it in terms of where to go. Maybe there's more in the --

MR. LOHAUS: You will find no recommendation in the Commission paper from the staff, but the recommendation of the working group in their report was the alliance option. That was the working group's recommendation.

But I want to emphasize again these are issues that are under consideration. There has been no decision reached, and you're correct. That paper does not have a recommendation there.

There are options that were provided for consideration, and --

CHAIRMAN CERQUEIRA: Well, I think, you know, the Commissioners said that they really value the input of this Committee into these kind of decisions makings, and I think here's a situation where, you know, we weren't even asked to participate or be involved, and so you know --

DR. NAG: We weren't even aware of it.

CHAIRMAN CERQUEIRA: Yeah. That's even more distressing.

And so what are the wishes of the Committee? So we can't be involved in this because it's been done. I mean, Ralph, we should see the final report, but should we make some recommendations to the Commissioners on this?

MR. LIETO: Well, I guess I'm going to kind of ask John. I mean I take it that the working group's sunset. The parties are still there, okay, and that whatever, you're waiting to hear back from the Commission. Is that what the next step is?

MR. LOHAUS: The paper is before the Commission.

CHAIRMAN CERQUEIRA: Well, when did it go into the Commission?

MR. LOHAUS: In May, but I want to make it clear --

CHAIRMAN CERQUEIRA: In May?

MR. LOHAUS: In May of last year, but again, there was no staff recommendation. There were items; there were options that were provided for consideration, and there's an expectation that the Commission has that there will be additional material provided to them to assist them in consideration of that paper and in reaching a decision at the right point in time.

So it's under consideration. That's why I want to emphasize these are issues that are under consideration. There's not a hard decision that's been reached, and they are issues that we're going to collectively need to continue to wrestle with.

One thought I'll pass on for consideration. We can provide a copy of the report to you.

CHAIRMAN CERQUEIRA: Well, we agree that that's critical to be done.

MR. LOHAUS: And maybe in looking at that report if you see areas where you believe there would be benefit and there are views that you'd like to provide to the Commission, it's an opportunity to

provided those.

DR. NAG: May I suggest that once you have provided us the report, we look through it, make a comment, and then send it to the Chairman, and then the Chairman can compile a joint report from all of us and send it to the Commission.

CHAIRMAN CERQUEIRA: I think that would be the best way to do it. I'd also like to personally, you know, contact the Commission and say that, you know, to not be involved or informed is really not taking advantage of the Committee and the time that we've put into it.

You know, in a sense I feel, you know, slighted. We're basically not -- you know, we have a Committee. We all spend lots of time and effort in coming to these meetings, and here's an issue, which is probably as important as Part 35 revision, and we've basically been left out of the loop.

MR. MYERS: If I could, Dr. Cerqueira.

CHAIRMAN CERQUEIRA: Yes.

MR. MYERS: I would say this. I don't think anybody on this Committee should feel slighted or anything. We at the working group level really, I think, spent a lot of time trying to make sure that we made interested parties or folks, stakeholders, as we

want to call them, aware of this, and there were a huge number of folks in different organizations that were contacted.

I will have to say, and as co-chair I will take the hit for this, is that I don't really think that we thought about ACMUI in that process. So if we -- if anything was wrong, we didn't think about you all, and the fact that although we know that you guys would have some input and concerns and questions about it, it's just thinking back on it is like I don't think that we, the working group, really looked at that thing, and that's important.

So what we'll do is we'll make sure that you get a copy of the report, and as you know, the Commission has not made a decision. The working group folks are still there, but we're kind of like old baseball players, I guess, or something. We're on the bench for a while, whatever.

So if the Commission decides that it needs more input, the Commission would have to decide that it would constitute the group, reconstitute the group, a new group. You know, I can't --

CHAIRMAN CERQUEIRA: I think that would be -- that should be done, but we'd still -- I think the feeling of the Committee is we should still get the

report and get some comments.

MR. MYERS: Sure.

CHAIRMAN CERQUEIRA: So Jeff and then Niki.

DR. WILLIAMSON: yeah, I would make a motion that the Chairman direct the ACMUI to review the report and subsequently develop a position or consensus within the Committee as to the wisdom of enlarging NRC's jurisdiction.

MS. WAGNER SCHWARZ: I second that motion.

DR. WILLIAMSON: To include NARM.

CHAIRMAN CERQUEIRA: Okay. Discussion?

(No response.)

CHAIRMAN CERQUEIRA: The motion --

MR. HICKEY: Well, Mr. Chairman, could I just clarify that? That's a resolution that does not necessarily relate to this working group report directly.

CHAIRMAN CERQUEIRA: Right.

MR. HICKEY: It can be taken as a separate issue.

DR. WILLIAMSON: But I think it's an important issue for us to consider --

MR. HICKEY: Okay.

DR. WILLIAMSON: -- and be aware of the

pros and cons. And there may be pros that I, for example, am unaware of, and I think it's well for this Committee to have a point of view --

CHAIRMAN CERQUEIRA: Right.

DR. WILLIAMSON: -- on this matter and be prepared to communicate it to the Commission at the appropriate time.

MS. WAGNER SCHWARZ: I agree. I think that this is a significant --

DR. WILLIAMSON: So this is really very serious.

DR. NAG: I think that we should, after we have reviewed this report so that we have an idea what the report --

DR. WILLIAMSON: That's what I just said. I said that the Chairman -- I move that the Chairman direct the Committee, the ACMUI, to review the final report of this group and then develop at our next meeting a consensus on the wisdom of enlarging NRC's jurisdictional mandate to include NARM.

CHAIRMAN CERQUEIRA: Well, review the report and make recommendations. You know, the wisdom to expand may not be part of it. I'm not sure we can -- so I think the recommendation to review and comment on the report is probably, you know, the more

appropriate.

Do we have a second on that?

DR. NAG: I would second the revised motion.

CHAIRMAN CERQUEIRA: Okay.

DR. NAG: And I would like to add a time line, please. I mean, by what time? Are we going to meet forever? Are we going to have a one month or you know? Are you going to write the report within one week? You know, some type of time line should be added.

CHAIRMAN CERQUEIRA: Well, how hard does the Committee want to -- a month? A month? Jeff, a month?

Okay. A month, good. All right. That sounds reasonable. So we had a second with the amendments.

Any further discussion?

(No response.)

CHAIRMAN CERQUEIRA: All right. I move that we vote.

MR. MYERS: I have one question --

CHAIRMAN CERQUEIRA: Yes.

MR. MYERS: -- just so we can cover this. How many members are on the ACMUI now? Eight?

MR. HICKEY: Thirteen.

MR. MYERS: Thirteen? Okay. So I'm just trying to figure out how many copies.

MR. HICKEY: We're not all here.

MR. MYERS: Okay. So we need at least 13 copies. Okay.

MR. LOHAUS: We'll try and get 13 copies to you today.

CHAIRMAN CERQUEIRA: Well, if you can get them today so that we can carry them home. How many pounds is this, 30?

MR. LOHAUS: It's a two volume report. It's maybe about, I'd say, a quarter to half an inch thick total. Does that sound about right, John.

CHAIRMAN CERQUEIRA: All right.

MR. MYERS: It's probably about --

MR. LOHAUS: This is available electronically also, Jim, on our Web site. So we can give you the URL for it also.

CHAIRMAN CERQUEIRA: I'm not sure it's critical to get it to the Committee today. I think we should make it available, and I think Angela could overnight it to people. If people want it electronically, I think that would be the preferred method.

But we have a motion that's been seconded and discussed, and I call for a vote on this. All in favor?

(Chorus of ayes.?

CHAIRMAN CERQUEIRA: And opposed? Abstentions?

(No response.)

CHAIRMAN CERQUEIRA: None. Okay. So I make the recommendation.

And how do people feel? Should I talk to the Commissioner about that this Committee feels left out, slighted?

MS. WAGNER SCHWARZ: Yes.

MS. HOBSON: I can hardly believe that a major policy change like this has just sort of slipped through with, you know, not very much public comment at all, and I think that's really not a very desirable thing.

And then I would also like to ask you: did you invite any patient groups to participate? Because patients are the ultimate stakeholders.

MR. LOHAUS: Jim?

MR. MYERS: I'm thinking. I think we did ask, but I don't believe that we had anybody come that I recollect. We did have some folks from some of the

public interest groups initially, but recognizing that medical is one part of this complex puzzle that we were dealing with, I'd have to say initially no. I don't think that there were anybody that were patient advocate groups that were there.

Also recognize that this report was provided to the Commission and thought we sought a lot of public comment and stakeholder comment on it, and I think that the working group did a really good job of trying to get everybody involved, what happens is that once the Commission makes a decision about whatever it wants to do, that's probably more in the realm of policy, and that's where more comment and more favorable things that would be coming from the public would be put into this as well.

And I think that --

CHAIRMAN CERQUEIRA: Right, but the problem with that is once you've got a draft of something, you've spent the time. It's much more work to undo something that's been created than it is to be involved in initial development and do it right.

And certainly without the input of, you know, certain patient groups -- and again, I'd like to see the involvement of the professional medical community. I think it's important.

MR. LOHAUS: Yeah, I hear you. I hear you. And we'll give you the listing of people that attended the stakeholder meeting, and that was part of the reason for holding that meeting, was to provide opportunity when there was a product that could be reviewed to give folks an opportunity to look at it and give the working group some feedback, but we'll give you the list of people that attended.

And we may not have had all the right people there, but I think the intent and our goal was to involve a cross-section of stakeholders.

CHAIRMAN CERQUEIRA: Well, we're not questioning the intent or the product, but it's just more of the process, and again, I'd like to thank Ralph for putting it on the agenda, bringing it to our attention.

MR. LIETO: Thank me or blame me.

CHAIRMAN CERQUEIRA: Okay. Now, let's everybody be back here by one o'clock. We don't want to come back any earlier.

(Whereupon, at 12:04 p.m., the meeting was recessed for lunch, to reconvene at 1:00 p.m., the same day.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:04 p.m.)

CHAIRMAN CERQUEIRA: I hope everyone had a good lunch. Dr. Williamson was observed to be taking part in the dance lessons in the hallway there. He does a pretty mean swing, but not too good on the tango.

(Laughter.)

CHAIRMAN CERQUEIRA: Just kidding, Jeff.

And now we're back to Dr. Ayers.

DR. AYERS: Yeah, hoping to pick up where we left off. Maybe we've got all of the questions out of the way, but I doubt it.

(Laughter.)

DR. AYERS: As I said, partial recognition, and what we haven't gotten into is the process of responding to the Board's applications and going back and forth and working out together where the endpoint will be.

CHAIRMAN CERQUEIRA: When will that happen. You know, obviously you can't do it until the regulations get approved, but once they get published, will you be able to initiate the process so that by the time it becomes law you'll be able to --

DR. AYERS: I defer that to John.

MR. HICKEY: Yes, we would do that prior to the effective date, but now the response has to reflect the discussions we've had yesterday and the work that the subcommittee and the staff are going to be doing as to what solutions are there.

But the reviews have pretty much been completed so that if you set aside the discussions yesterday and today, we could go ahead and notify all of the Boards the results of the review.

CHAIRMAN CERQUEIRA: What about the Boards that aren't affected? You know, it looks like the AB&M, the ACR, CBNC, and some of the other exams would --

DR. AYERS: All are affected except two.

CHAIRMAN CERQUEIRA: Okay, and you're going to tell us which two.

DR. AYERS: Yeah.

MR. HICKEY: Well, one is at the Board of Nuclear Medicine. They've already been notified.

DR. AYERS: That's correct, and the other one is the CNBC; is that right?

CHAIRMAN CERQUEIRA: CBNC?

DR. AYERS: CBNC.

MR. HICKEY: Well, tell people what that stands for.

CHAIRMAN CERQUEIRA: Certification --

DR. AYERS: Cardiologist -- oh.

CHAIRMAN CERQUEIRA: Certification Board of Nuclear Cardiology.

DR. AYERS: Yeah. In fact, they had to manage informing the Board rather late, and compared to others and actually incorporated all of the requirements right into it. So it's really straightforward.

CHAIRMAN CERQUEIRA: I didn't mean to take you off on a tangent there, Bob.

DR. AYERS: Okay. The next slide.

I think you're all aware of the problems which are kind of reflective of many of the Boards with the American Board of Health Physics, for example. They don't have the specific requirements which are required by the regulations.

Now, mind I'm not including any of the discussions in the last couple of days, and if we do have some rule changes, we'll have to all go back to the starting point on this whole thing, but this is purely as it relates to the existing draft of new 10 CFR, Part 35.

So they don't meet the one year full-time radiation experience in medical applications, nor the

corresponding written preceptor statement.

Next slide.

CHAIRMAN CERQUEIRA: Well, Bob, can we go back to that?

And I guess, you know, again, these discussions I'm sure we --

DR. AYERS: Well, I will add at the end I list all of these problems for discussion. I was just pointing to individual --

CHAIRMAN CERQUEIRA: Okay. So the preceptor statement, there's no way we can require that and then the one year training?

DR. AYERS: I go through the individual Boards --

CHAIRMAN CERQUEIRA: Sure, okay.

DR. AYERS: -- and then we go to the general discussion and then relist all of the across the board features --

CHAIRMAN CERQUEIRA: I apologize.

DR. AYERS: -- with Boards.

All right. The letter to the American Board of Nuclear Medicine did say that we were planning to grant NRC recognition for the modalities they requested, except for the RSO under 3550(a) because, again, they don't -- they have not presented

evidence that they meet the one year and the preceptor statement, although most of the medical boards, they can become radiation safety officers for their specific modality based on their authorized user status, and that includes medical physicist.

CHAIRMAN CERQUEIRA: Right.

DR. AYERS: What they can't do is qualify for broad scope RSO big programs under A.

Next slide.

As I said, we just see no issues on this one.

Next slide.

The only thing I guess I'll add as a comment to that, they're only requesting 290 and the regulation requires that the preceptor have 190 and 290 experience, and I agreed with them in the draft letter that it would seem pointless that they have 190 experience for their preceptor since they're not authorizing that modality.

Here's the key point. For radiation safety officer authorizations, a large number of the Boards, essentially all of them or -- I'm sorry -- all that asked, but a great number asked for recognition under the full radiation safety officer qualifications under 3550(a), but none at this point has been able to

document they meet that one time or one year full-time medical experience under supervision of a qualified radiation safety officer, nor do either present evidence for the preceptor statement that goes along with that.

MS. McBURNEY: Bob, if the American Board of Health Physics did change their requirements for certification to include a preceptor statement and documentation of experience --

DR. AYERS: Yeah, that's really coming up on the next slide.

MS. McBURNEY: Oh, okay.

DR. AYERS: Okay. But as I said, many of the Board diplomates would qualify under 3550(c). In fact, the only one that wouldn't would be that -- I don't remember that acronym accurately, but that specialty Board for Nuclear Medicine.

CHAIRMAN CERQUEIRA: CBNC or --

DR. AYERS: No

MR. LIETO: American Board of Science and Nuclear Medicine?

DR. AYERS: American Board of Science and Nuclear Medicine, that one, because they don't have any corresponding authorized user status in any other category, nor are they asking for one.

Next slide.

With the medical physics authorizations, again, for both ABR and American Board of Medical Physicists -- Physics, they have lack of, as we've talked about many times, the Board requirements for the specified trading in all of the modalities and the corresponding signed preceptor statement.

And we already talked about the partial recognition, and this could apply to all Board, and in the next slide, I think we get into the big generic issue, I hope.

CHAIRMAN CERQUEIRA: Before we go on, Jeff, do you have a question?

DR. AYERS: Yeah.

DR. WILLIAMSON: I recently reviewed the eligibility requirements for ABR, American Board of Medical Physics. They certainly do require signed letters testifying to the competence. So I'm wondering what is the --

DR. AYERS: That's the next slide.

DR. WILLIAMSON: -- legal deficiency of that requirement compared to the --

DR. AYERS: Okay. I intend to talk -- I believe the next slide has that.

DR. WILLIAMSON: Okay.

DR. AYERS: Yeah, the next slide, please.

The generic issue is, as I said, applicable to all the Boards except the Board of Nuclear Medicine and the Board of Nuclear Cardiology, is the absence of the exactly specified signed preceptor statement or statements in accordance with the new Part 35 requirements for the various Board certification processes.

Now, ABR, for example, asks for a reference letter for a physicist and a --

DR. WILLIAMSON: From a radiation oncologist, I believe, too.

DR. AYERS: Well, in one they call it a reference letter, and in the other one they call it something else. The name escapes me. Sometime somewhat similar.

The problem is -- and the Boards could easily if they chose or maybe I shouldn't say "easily." The Boards could -- one option would be to change their procedure. The biggest blocking point from any of the Boards is a signed preceptor statement. They have --

CHAIRMAN CERQUEIRA: Well, tell me --

DR. AYERS: -- requirements that are similar, but not the same.

DR. WILLIAMSON: What's missing from the ABR when they say letter of reference from a certified physicist and a physician? What's wrong with that?

DR. AYERS: Two things that stick up immediately is they don't say that they've supervised them and they've been -- they're trained and qualified in the specific numbered parts of the regulations.

And the second one is there's no requirement that that letter, recommendation, reference -- I think it's called recommendation in place of reference and others -- there's no requirement on the part of the Boards that those be from what we would deem a qualified preceptor, that is, an authorized user that is authorized for those modalities.

CHAIRMAN CERQUEIRA: Jeff, how difficult an issue would that be to get that letter? I mean, is most of the training done by authorized user or AUP or AMP?

DR. WILLIAMSON: I think largely that is so. I think the major problem would be that the certificate itself would have to be amended to specify HDR, gamma stereotactic, and teletherapy. I think that is the big blocking point, is that there is no mechanism by which, you know, footnotes can be made to

the diplomate certificate indicating the different modalities.

You know, this letter is not something they're going to be willing to share with you.

DR. AYERS: Well, it wouldn't be if they chose to have some subset and say we require the appropriate preceptor statement or this subset and that's a partial part.

DR. WILLIAMSON: Yeah, but they don't do that for any subset. They're don't do it for Cobalt --

DR. AYERS: I know that.

DR. WILLIAMSON: -- 60, HDR or gamma stereotactic, and it's unlikely they will.

DR. AYERS: It's a little more straightforward for the medical Boards, for ABR, for radiation oncologists, for pharmacists. The same problem; it's across the board with all of these Boards. I keep forgetting.

None of the medical Boards that I've reviewed have at this point presented any evidence to us that they require and goes in the file for their Board diplomate, the required certification.

The other alternative, of course, is changing the requirements, which you've already

presented to the Commission.

The other alternative under the existing regulation would be for the Boards to adjust the requirement.

And some of the medical Boards may be a little further away in that the letters they require are from their clinical director who may or may not be active or may or may not be what we would deem an authorized user. I don't know. We've got to ask these questions.

CHAIRMAN CERQUEIRA: Ralph, you know, you're not weighed down by all of the baggage of past discussions. How do we get out of this and come up with a way that --

(Laughter.)

MR. LIETO: What I see is what we're trying to do is put a square peg into a round hole.

DR. AYERS: Exactly.

MR. LIETO: And I think --

CHAIRMAN CERQUEIRA: So how do we shave it?

MR. LIETO: It seems like the discussion I've been hearing is how do we get the Boards to do this. How do we get this to change? And I don't think that's the way to go. Okay?

I was thinking at first, well, maybe there should be sort of this form letter of recommendation that says, you know, "I, Dr. So-and-so, attest to the fact that Physicist XYZ meets the criteria for taking the Boards because of his experience," and lists some of these modalities, but these things are going to change with time.

DR. AYERS: And certify that --

CHAIRMAN CERQUEIRA: That he's competent.

MR. LIETO: Well, the Board exam --

CHAIRMAN CERQUEIRA: That the person is competent.

MR. LIETO: You know, passing the exam would establish his competency. So my feeling is that I think any discussion of trying to get changes in the Boards or applications to the Boards is going to be very lengthy, time consuming, because they have to go through their mechanisms of approval, and I don't really think in the long term it's going to solve the problem. I think the issue is, as we discussed this morning, is change in rulemaking.

CHAIRMAN CERQUEIRA: The rulemaking.

MR. LIETO: I really think that's where we have got to go.

CHAIRMAN CERQUEIRA: Yeah.

DR. AYERS: And that's why I said I'm confining my remarks to not changing the rule. The rule changes; the whole thing starts over. It's a whole new ball game with regard to what I'm presenting.

CHAIRMAN CERQUEIRA: And, Richard, in terms of the RSO, is that also the situation?

DR. VETTER: Yeah. For example, the American Board of Health Physics certifies people in all areas of health physics. If they changed their certification process, they would need to have a preceptor statement for everyone whether they're going to be in medical or not.

I mean, it just doesn't work. Like Ralph said, it's a square peg in a round hole or vice versa. And they're not going to change it.

CHAIRMAN CERQUEIRA: No. In nuclear medicine, I mean, you know, the preceptor statement specifically lists the isotope and the number of hours that people have had, and we've been using those preceptor statements for the longest time. Isn't that something that could be generalized?

DR. AYERS: Well, we've been using the preceptor statements under the old rule for non-Board certified individuals, physicians, medical physicists,

RSOs, and so forth. That's always been there.

What's new with new Part 35, and I think why a lot of people missed that it was a change is that the Boards are now being vetted against the training and experience requirements in the second and sometimes third parts of the rule.

And I don't know how the Boards that are recognized now by us achieved that process. That was before my time.

CHAIRMAN CERQUEIRA: And, Ralph, Jeff, and Richard, the Boards have been approached and it's not doable?

DR. VETTER: Well, I've talked with two Boards, and it just doesn't fit their objective. They're looking to certify the competency, the knowledge base, and that really has nothing to do with where they got it. It just doesn't fit for them.

CHAIRMAN CERQUEIRA: And it's not specific. Again, for some of these things, for the agents.

DR. VETTER: Right.

DR. NAG: Yeah, I have a problem. Directly in radiation oncology is that in the Board certification it says you are now qualified to do radiation oncology on the whole. I may never want to

do a gamma knife, and if you say you are going to require everyone to have that knowledge, you're not going to have many people, you know, passing the Board.

You know, they want to certify a general overall knowledge. Now, you can use that knowledge, and then if you're going to do gamma knife or some of these special procedures, you can take some special training for that.

But you cannot make that a requirement for every radiation oncologist to know about gamma knife.

CHAIRMAN CERQUEIRA: But if we had an interventional cardiologist, he would say, "Well, why can't we take them and have them do a limited subset of training and experience to be able to meet their requirements, to sort of be the sole user?

DR. NAG: Yeah, but the problem is you need an overall general knowledge, and then you need to supplement that with specific knowledge. You can't just say I want to have only the specific knowledge without the general fundamental knowledge to back you up.

So if you do a separate requirement just for gamma knife, it is not good because you can't just make, you know, 200 hours at gamma knife without

knowing the rest of the general radiation basics.

DR. WILLIAMSON: There's another problem. Even if the Boards adjusted their procedures so that prospectively new candidates complied with these rules, it's not retroactive. The problem would still exist that the vast majority of Board certified physicians and physicists could not meet these regulatory standards.

DR. AYERS: Well, I think the grandfathering might be a large part, but --

CHAIRMAN CERQUEIRA: So is that possible under the --

MS. McBURNEY: Yeah, grandfathering.

DR. AYERS: That's my next slide, which has some issues there, but I'll get to that.

CHAIRMAN CERQUEIRA: Why don't we go to the next one? Are you done with this one?

DR. AYERS: Yeah, I think the problem is well identified. There are really three branches to this, work to the existing Part 35, and most Boards won't qualify and will have to come in under training and experience; change the rule and get it where most people are happy. I don't know if you can ever make everybody happy.

CHAIRMAN CERQUEIRA: That's not our

mission here.

DR. AYERS: Okay. Let's go to the next slide.

CHAIRMAN CERQUEIRA: But, again, we do have this subcommittee that's going to look at this and come up with some recommendations on how to resolve this.

DR. AYERS: And I guess one question you raised was that, well, the Boards have responded to this. Well, the letters haven't gone out yet. So our query to them about this hasn't went out to them yet. So there hasn't been any forma interchange between the Boards and NRC until those letters go out.

Okay. On the grandfathering, I wasn't prepared to talk about it last time, and I wasn't sure, and I agreed that the language was a little ambiguous, but the states in consideration are very precise. For medical physicists, pharmacists, and RSOs, which is really not relevant, it's mostly for medical physicists. What the statements in consideration very precisely say is you will get what you have. If you're an authorized teletherapy physicist, that's all you get. If you're authorized for teletherapy and HDR, you get those.

You get what you have now. You don't get

a broad recognition.

DR. WILLIAMSON: Which undercuts the last point that was made. So there is an issue with grandfathering the previously boarded --

DR. NAG: What about authorized user, NRC authorized user?

DR. AYERS: I'm sorry?

DR. NAG: Authorized user? I mean, are they not grandfathered?

DR. AYERS: No, the authorized user is 35.57(b), which wasn't an issue. The language differs in that a little, and it's much clearer. So this was the issue item from last time.

DR. WILLIAMSON: Can the statements of consideration be modified? Are they as unmodifiable as the rule?

MR. HICKEY: The answer is yes, and that will be within the scope of what the subcommittee and the staff looks at. Certainly if the rule can be changed, the statement of consideration can be changed.

MS. McBURNEY: But not for this printing. It would be a new rulemaking and a new statement of consideration, right?

MR. HICKEY: If the question is how

quickly can it be done, it's easier to change something that's not a rule than it is to change a rule.

DR. AYERS: I think the Commission would probably have to be on board on that, but don't hold me to that.

MR. HICKEY: That's correct.

DR. AYERS: And you have presented your views to the Commission, and that's outside of the scope of what I'm talking about.

MR. LIETO: Bob, could you just refresh my memory? What's 35.57(b)?

DR. AYERS: That's the grandfathering clause. That means everybody that is currently listed as an authorized user at the time the new Part 35 takes effect will be grandfathered for the authorities that they now have essentially.

MS. McBURNEY: I understand all the stuff about the Board certification was in the proposed rule as it is in the final, but not a whole lot changed.

DR. AYERS: I was not involved in the rulemaking. So I can't -- if somebody else wants to speak to the history, I know it went through several revisions because at one time there was consideration of a written test on radiation safety, and where the

changes occurred along the path, I guess Marjorie is coming up to the microphone. She's more knowledgeable of the history of rule development than I am.

MS. McBURNEY: And whether there were comments about that or did people just sort of assume that their Boards would be accepted?

DR. AYERS: I'll let Marjorie address the question.

MS. ROTHSCHILD: Okay. Well, the proposed rule published in August of 1998, the language that is now at issue was virtually identical in the proposed rule, and I can point you to that. Okay? It's 3550 -- if we're taking like authorized medical physicist as an example, that proposed rule language was, "The licensee shall require the authorized medical physicist to be an individual who," and then under A it states, "is certified by a specialty Board whose certification process includes all of the training and experience requirements in Paragraph B of this section and whose certification has been approved by the Commission."

Now, that last phraseology there --

DR. AYERS: That's the same, yeah.

MS. ROTHSCHILD: -- may have been changed slightly, just the last phrase, and there was a

provision, you know, in this proposed Rule 3551 for passing an examination, but the language at issue, taking this provision as an example was virtually the same in the proposed rule published August '98.

And the kind of brief review I've had time to do in terms of comments and responses in the statements of consideration, I didn't see this precise issue as raised by commenters or any of the professional societies.

DR. AYERS: Yeah, I looked through that. There were no comments on this issue that I could find in my review through the package. The intent of this whole thing was to take naming the Boards out of the regulation where it prohibited us from adding or deleting new Boards or Boards that changed without -- we'd be rulemaking to add or delete the Board as it exists now in the old Part 35.

And I guess when you say we're going to recognize Boards, you've got to put something in, and this appears where the miss occurred, at least from the perspective of the Committee here. You've got to put something in that says this is what it takes to be qualified to be recognized.

Now, the recognition criteria could be different obviously than what they are if we're

rewriting the rule or if you went back listing them in the rule itself, you again tie Board recognition to rulemaking process in the future.

CHAIRMAN CERQUEIRA: All right. Jeff?

DR. WILLIAMSON: I think a couple of comments have been made by the Commissioners and maybe others on the staff -- I think Don Cool -- that there was something that could be done in the implementation of these regulations that would at least temporarily ameliorate the consequences or mitigate the consequences of this problem, and I'm wondering if John or Bob could expand on this.

DR. AYERS: I'll defer to John.

MR. HICKEY: I don't think I can add anything to what's been said. We agreed that --

DR. WILLIAMSON: I gathered that this was -- this is what I understood them to be implying, although it wasn't made clear, that there was the possibility when the regulations are implemented that basically a hold could be put on some component, subcomponent of the regulations if it turned out there was an unforeseen difficulty in implementing them without postponing the implementation of the rest of the new Part 35 requirements.

DR. AYERS: Yeah, I think that can be

considered. However the Commission, they haven't addressed the issue of a fragmented effective date directly, but they's stated that they don't want to revise the rule in pieces.

So if there were a proposal to implement it with different effective dates for this part, that would be an issue, but I think that does need to be considered nevertheless.

DR. WILLIAMSON: So that is a possibility. That was my question.

MR. HICKEY: Everything is a possibility.

DR. AYERS: Yeah, I think most of what you're talking about now is at the Commission level, and it was great that everybody had a chance to bring these issues to the attention of the Commission yesterday, and now it's on the radar so to speak.

I can't predict what will happen.

CHAIRMAN CERQUEIRA: Okay. We have a question from the audience.

MR. UFFELMAN: I'm Bill Uffelman, Society of Nuclear Medicine, ACNP, but on behalf of the American Board of Science and Nuclear Medicine.

With the six month delay or call it the six month delayed effective date of the rule, those -- and you made the comment somebody who is already an

RSO is an RSO and, you know, they're grandfathered. But somebody who was previously an RSO, but is now working as an RSO because they've changed jobs or whatever, can they go back and be an RSO without going through the whole rigmarole? That's question one.

Question two, those --

CHAIRMAN CERQUEIRA: Wait. Why don't we get an answer to question one, and then we can --

DR. AYERS: Question one, I don't know. I haven't looked at that issue.

CHAIRMAN CERQUEIRA: That was easy.

MR. UFFELMAN: Okay. Question two, ABS&M's exam is given in June at our annual meeting in L.A. this year. Those who pass the exam in June and become diplomates of ABS&M, because they're in this window between the March publication and September-October effective date, what is their status, you know? Under which rule are they applying for recognition of their qualification?

DR. AYERS: Well, they're applying under the current Part 35 until such time as the new rule becomes effective.

MR. UFFELMAN: Okay. So that's different than what you said last year. That's why I was checking.

MR. HICKEY: This is John Hickey. Let me point out that they have to be listed on a license. It's not good enough just to be certified as of the effective date of the new rule.

MR. UFFELMAN: So they've got to have this RSO job lined up for, you know --

MR. HICKEY: We said -- I agree I don't offhand know the answer to the first question because the rule says "identified." So I'd have to get an interpretation as to whether that means currently identified or previously or currently.

But the answer to the second question is you have to be certified, and if you haven't been listed on a license, you need to get listed on a license before the effective date of the new rule.

DR. AYERS: Yeah, a job offer wouldn't do it. I mean, you'd have to actually go through the process and be listed on the license to be grandfathered.

CHAIRMAN CERQUEIRA: All right. Well, I guess we overlooked a few things at different levels, and I think we've identified the problem. We've spoken to the Commissioners. We've established a subcommittee that's going to look at it, and we kind of need to address it possibly as a new rule.

I guess the one question is that for the Boards who have already applied and have been reviewed and have met most of their criteria, I don't see any reason that they should be held up. Is that the feeling of the Committee?

There's no --

DR. AYERS: Well --

MR. HICKEY: Wait a minute. He's asking the Committee.

DR. AYERS: I'm sorry.

MR. HICKEY: Sorry.

DR. WILLIAMSON: And these Boards, just to refresh our memory are the nuclear medicine, two nuclear medicine Boards, right?

MR. HICKEY: That's right.

CHAIRMAN CERQUEIRA: What about the ACR?

DR. NAG: ABR you mean.

CHAIRMAN CERQUEIRA: ABR. I'm sorry.

DR. AYERS: A preceptor issue, a preceptor statement issue.

DR. WILLIAMSON: It's important to recognize. It sounds like right now radiation oncology certification is not going to make it for either the brachytherapy, teletherapy, or the radiopharmaceuticals. Only nuclear medicine

certification.

DR. AYERS: The same applies to the radiopharmacy and the medical physics and RSO. It's essentially everything else.

DR. WILLIAMSON: So the scope of the disaster widens.

CHAIRMAN CERQUEIRA: It's definitely a problem.

Ralph?

MR. LIETO: I just wanted to make maybe a comment regarding the grandfathering. You said you weren't too sure about if somebody was not listed now, but had been previously, would they be grandfathered. I guess --

DR. AYERS: Yeah, and I don't know, and there is some provisions in our current regulations that gives a window of time in which you can --

MR. LIETO: My suggestion was going to be as long as that meets the recentness of training requirement --

DR. AYERS: That's the window.

MR. LIETO: -- that they be allowed to grandfather.

DR. AYERS: Again, I don't know at this point without --

MR. LIETO: Just a comment.

DR. NAG: One possible solution for the short run, since we now have a separate meeting, until the results of the subcommittee comes out -- that means the new will not be implemented until the subcommittee comes out.

CHAIRMAN CERQUEIRA: I don't think we can do that procedurally. I mean, basically the Commission has made the decision, I think, which was supported by the Committee, you know, that they didn't want to fragment the rule out, break it out in different ways, and I think the option that has been given to us is basically implement a rule and then come up with a new rulemaking, which is part of the charge of this Committee.

But in the meantime I'm not sure it's in the interest of the stakeholders. If some of the Boards basically have been approve by this new standard, I think it would make sense since they weren't affected as directly by some of these other ones to basically let them get approval.

DR. WILLIAMSON: Well, I think I concur with our chairman. There seems to be no reason not to go ahead and recognize the certifications of the two nuclear medicine Boards. It sounds like if the

fragmented date of implementation strategy is used, it could be carefully calibrated to avoid the 35, 200 and 100 modalities and focus on the 300, 400, and 600 modalities where the problem occurs.

DR. AYERS: Well, I think the last two days have introduced a reason. Now that the Board certification process may be back on the table, and what we're prepared to do now may not be valid tomorrow.

(Laughter.)

DR. WILLIAMSON: Well, that's a good point.

CHAIRMAN CERQUEIRA: All right, but the decision on this is going to have to be made soon, very soon, I mean, and if Congress gives approval to go ahead, then I think the Commissioners are going to need to make some decision on how to deal with this.

I didn't get the feeling from yesterday's meeting that they had a solution for us. They're willing to have us look at it, but there's no immediate resolution that's been put forward by the Commission, by this Committee, or by the NRC staff.

DR. AYERS: And I think if the rule goes through as planned, we'll immediately get those letters out. One of them is, in fact, granting

recognition to the second diagnostic Board, and we've accomplished what you're asking for. It's just merely we're just waiting until we know for sure which way to jump.

CHAIRMAN CERQUEIRA: Right.

DR. NAG: And I agree with having the two Boards, you know, approved, but what is going to happen with the other four or five Boards? Once implemented, I mean, you know, what are the consequences of that?

CHAIRMAN CERQUEIRA: Well, the people that are already out there, I mean, should it change? They would be grandfathered, correct?

DR. NAG: No, but the new graduates are coming out this year.

DR. VETTER: But they would be approved under the -- filling out all of the forms of the preceptor statement, training, and so forth.

DR. AYERS: And these letters are going to --

CHAIRMAN CERQUEIRA: And the people who would be most affected would be the people who are starting training now; is that correct?

DR. NAG: No.

DR. AYERS: Well, the letters going to the

Boards are not denying recognition. It's asking questions. What I'm getting from the Committee is we may not get the right answers back, but it's not going out and saying you're not qualified. It's saying we don't see where you do A or B, and could you please advise us how you do this?

CHAIRMAN CERQUEIRA: Yeah, I think there was precedent for some of this. I mean, when my predecessor Barry Segal was here, there was quite a little controversy for the people who didn't have Boards but were trying to meet the requirements for authorized user under training and experience as to whether there could be two 500 hour blocks, whether they were simultaneous or concurrent, and a vote was taken that, you know, if there were issues, it could come to this Committee for review.

I think we maybe reviewed one or two, and potentially this Committee could assume some of that responsibility, but we're talking about large numbers now if we're talking RSO.

DR. AYERS: Yeah, the issue of multiple 500 hour blocks was addressed in a letter from the Chairman. I'm trying to remember the addressee right offhand, but that we wouldn't -- for a radiation oncologist for a number of different modalities, we

wouldn't sum those 500 hour blocks. That was addressed in a response from the Chairman.

CHAIRMAN CERQUEIRA: Well, we need to do something, and I think it's going to be implemented, and we need to initiate this process. It doesn't seem like we've gotten any indication that the guidance documents would deal with it effectively, and it seems like the new rule may be the only way to do it.

And I guess the best thing would be to try to get this started.

DR. AYERS: I think the problem is guidance is intended to tell you or to provide information how to comply with the rule not change the rule.

DR. WILLIAMSON: Well, that's correct, but the guidance, you know, it would seem to me we've made the recommendation as a Committee that the guidance should bend over backwards within the confines of the rule as written to preserve as much of the existing recognition of Board certification as possible, and I still think you should take that as your goal.

MR. HICKEY: Yes. From what our review has indicated so far, it's clearly there is an issue with medical physicists and RSOs. There may be more flexibility to soften the impact with respect to the

authorized users.

DR. WILLIAMSON: Can you give us your draft guidance on how to -- what would be required to establish your screening criteria, so to speak, for establishing compliance with the authorized medical physicist provisions?

DR. AYERS: I can say all that I'm using now is the rule. That's the guidance, and the corresponding statements of consideration.

MR. HICKEY: We will do that. We're going to put a priority on addressing this first issue of what needs to be done to fix the rule, but we also will do that.

We have a letter from I believe it's the American -- from AAPM that has a proposal that we need to respond to.

CHAIRMAN CERQUEIRA: All right. Niki.

MS. HOBSON: Well, this morning one of the speakers referred to that there could possibly be a transition period where there would be some enforcement --

MS. McBURNEY: Discretion.

MS. HOBSON: -- discretion. Could that apply in this instance?

And also, what is the absolute shortest

time that this rule could be amended? What is the absolute shortest time?

MR. LIETO: Not amended, but rewritten.

CHAIRMAN CERQUEIRA: Not amended, but, well, just a new rule dealing --

MS. HOBSON: The new rule, the new rule.

DR. NAG: IBS.

CHAIRMAN CERQUEIRA: John? Best case?

MR. HICKEY: I can't comment on that.

DR. NAG: IBS.

DR. AYERS: The only comment I'd have is this is not an enforcement issue. It's a licensing issue in a sense, an indirect licensing. It's kind of unusual. We haven't been in this kind of space.

DR. DIAMOND: Bob, I actually disagree with that. Dr. Frant earlier today was very clear, 100 percent crystal clear that there's going to be some leeway with respect to how implementation is done, interpretation, maybe windows for implementation and so forth.

So please don't be as strict as you're telling us.

DR. AYERS: Oh, no, it's just wording. Implementation I have no disagreement with, but all I just said is it is not an enforcement issue. It's

clearly an implementation issue. Ms. Hobson presented it as an enforcement issue, and that it isn't.

Implementation, which she talked about, of course it is.

CHAIRMAN CERQUEIRA: The sense that I'm getting from the Committee is that, you know, we kind of agreed that we were correct on the nuclear medicine aspect of training and experience and Boards, and we should probably once the rule goes into effect implement that in the sense of approval of the Boards that have been reviewed and found to meet the criteria.

And I don't think -- that pretty much covers all of the stakeholders for nuclear medicine, but then we've got this other problem with, you know, potentially the radiation oncologists authorized users, but definitely with the radiation safety officers and the medical physicists, and we haven't really come up with a solution, and I think we kind of need to escalate this to, you know, maybe have a -- we met with the Commissioners yesterday. I think we were just kind of, you know -- the full implications of this were made known then.

You know, maybe we should try to talk to the Commissioner again, talk to Commissioner Meserve

to sort of see what the options are. You know, maybe Richard on behalf of the Committee and I could talk to him to see what the solutions would be.

Is that a reasonable way to go forward on this?

MR. LIETO: Well, I guess I'm a little confused now. Where is the subcommittee that was charged this morning fit into this?

CHAIRMAN CERQUEIRA: Well, the subcommittee would basically do the leg work. The thing is there's a whole bunch of unknowns. You know, how much can be incorporated in guidance? How much could be incorporated in grandfathering? Can we conceivably stagger the implementation, which is something that the Commissioners have said they did not want to do?

Nobody can give us a time line for the new rulemaking, and you know, we kind of need to have that information to see how we can basically solve it.

DR. WILLIAMSON: Well, I was going to suggest maybe a motion that we could vote on, that the ACMUI recommends that the staff petition the Commission to stagger the dates of implementation of the training and experience requirements to preserve the existing training and experience requirements for

radiation oncologists, authorized medical physicists, nuclear pharmacists, and radiation safety officers until such time as a revised regulation can be implemented.

CHAIRMAN CERQUEIRA: Do we have a second on that?

DR. NAG: I'll second the first place.

CHAIRMAN CERQUEIRA: I'm sorry?

DR. NAG: What you were asking in the first place.

CHAIRMAN CERQUEIRA: Right, right.

DR. NAG: You know, I second that.

CHAIRMAN CERQUEIRA: Yes, so you second it.

DR. WILLIAMSON: I just think we need to think outside of the box here a little bit, and that we should not impose a very confusing and conflicting transitional structure on the community if there is some possibility of avoiding that, given that everybody -- there's a general consensus among the Commissioners, the staff, and the regulated community that this needs to be addressed by a rulemaking initiative.

So to me it only makes sense to avoid imposing a very confusing and flawed system upon the

regulated community for a brief interval of time.

CHAIRMAN CERQUEIRA: And fully assuming some responsibility ourselves for not having clearly identified the problem that is --

DR. WILLIAMSON: Everybody screwed up on this, and there's a lot of blame to be shared for why we're in this position, but it only seems like the rational thing to do.

CHAIRMAN CERQUEIRA: Ruth?

MS. McBURNEY: My only comment on that is that I don't think it would be the proper mechanism for the staff to petition the Commission; that we as a Committee can make that recommendation.

CHAIRMAN CERQUEIRA: Right.

MS. McBURNEY: But I don't think putting that responsibility on the staff to go to the Commission.

DR. WILLIAMSON: I would amend it then to say that the ACMUI --

CHAIRMAN CERQUEIRA: Okay. That's appropriate.

DR. WILLIAMSON: -- recommends to the Commission and otherwise unchanged.

DR. AYERS: Marjorie, you were wanting protocol input, is waiting.

MS. ROTHSCHILD: Well, actually not on this particular motion. It was just Dr. Cerqueira's request for some information on a time line for rulemaking. I didn't mean to interrupt.

CHAIRMAN CERQUEIRA: No, no, no. If you've got some information factually that's good.

MS. ROTHSCHILD: Oh, okay. I was going to say generally with rulemaking under the Administrative Procedure Act, you have to have notice and comment. In other words, you give people notice as in a proposed rule, what you're planning to do, and then there's an opportunity for comment, which of course, is what occurred in this rulemaking.

Now, the duration of that comment period, you know, it can be very short or it can be, you know, very long.

I'm sorry?

MS. McBURNEY: Is there a minimum? We in the states have a minimum number of days --

CHAIRMAN CERQUEIRA: Comment period?

MS. McBURNEY: -- for comment.

MS. ROTHSCHILD: Well, the thing is there are other legal requirements, I guess, that figure into the comment period. Typically we have to allow for a minimum usually of 75 days, and so there are

some other -- besides the Administrative Procedure Act, there's some other statutory requirements, but I know that, you know, there have been comment periods in the past as short as two weeks.

The problem is people don't generally consider that. Usually what we get are requests for extension of comment period times.

Now, as far as, you know, shorter rulemakings, it's possible you can have immediately effective final rules, but those, the agency is subjecting itself to -- it becomes vulnerable in terms of the legal challenge when you have an immediately effective final rule.

There's also something called a direct final rule, but my understanding is for that it has to be an issue that's not controversial. I think based on all this discussion we could not say that.

So I hope that's somewhat helpful in terms of the rulemaking process and time periods.

DR. NAG: Do you have like a number out of the hat? Would you say like one year, two years, five years?

MS. ROTHSCHILD: Oh, for the duration of a rulemaking?

DR. NAG: From now till when the new rule

becomes --

MS. ROTHSCHILD: I mean, it depends on how long your comment period is.

DR. NAG: Minimum, minimum.

MS. ROTHSCHILD: Minimum?

DR. NAG: Overall from today.

MS. ROTHSCHILD: I can't make -- I mean I can just speak to what rulemakings that I'm aware of, you know, how much time has been consumed. Sometimes, you know, because of, say, statutory requirements where we have to act, you know, we can do start to finish in less than a year, but that --

CHAIRMAN CERQUEIRA: Let me ask Richard and Jeff and Ralph. Is this controversial? Do we anticipated that there will be --

MR. LIETO: That's a good question.

CHAIRMAN CERQUEIRA: -- groups --

MR. LIETO: My feeling is it appears from the discussion here that everybody is on the same page. I don't really think -- I think what should happen -- you know, I think in all due respect to Jeff's motion, I think we're a little premature.

I think, first of all, the rule hasn't been published yet. Okay? And we know what the problem is. So with the Committee already being

charged, and I guess I would ask if it's possible that they could come back with some proposal 30 days, you know, 45 days from now, and then turn it over to staff for the rulemaking process.

I mean if we had that and it's not controversial, isn't it possible we could have this all done by the end of the year?

MS. ROTHSCHILD: You know, I can't make any commitment. I just think the amount of discussion that the subject of training and experience generates, that that one aspect of direct final rule in this case I doubt, you know, whether this rulemaking, you know, would be appropriate for a direct final rule.

But you know, I'm just speaking now, you know, personally.

CHAIRMAN CERQUEIRA: Certainly based on my experience with this rule, I mean, you've got a public comment, drafts, publish the draft. People get to respond. You've got to respond to the questions that you've gotten, and it's got to be published again for another public comment period. It's going to take a while.

DR. AYERS: And there's the internal process, too, which includes the Commission's approval and the publication period.

CHAIRMAN CERQUEIRA: And OMB.

DR. AYERS: And OMB, yeah.

CHAIRMAN CERQUEIRA: Ruth.

MS. McBURNEY: Looking at the issues of the attempts to try to get more uniformity of the requirements throughout the country, I would prefer that these rules go ahead and go into effect, and even if people have to be authorized as authorized users and medical physicists under the alternate training and experience, in the meantime, before we can get these other proposed rules because it may take up to two years to do that.

In the meantime the states are going to have to start working on compatibility rules and so forth, and to have that total lag on all the rules and especially on the training experience trying to keep those more equivalent, that would be problematic.

CHAIRMAN CERQUEIRA: I agree with that.

So we have a motion.

DR. WILLIAMSON: I'm not sure I understand the point. It seems like that is going to happen if the implementation dates are not modified in this staggered way, the states are going to have to approve Part 35 as it is now within three years, and then in another 18 months a new modification of the rule is

going to come along, and then they're going to have to start working on that at the same time.

It seems to me it would make sense to leave the part alone that everybody agrees needs to be changed, implement the rest, and then when the final rule comes out, then the state should start working on it.

CHAIRMAN CERQUEIRA: Ruth?

MS. McBURNEY: No, I think that by the time the states get to the point of actually or many of the states get to adopting compatible rules, we would have at least a proposed change ready to go, and they could enfold that into their proposed rules.

DR. WILLIAMSON: But what would happen is we would propagate this error through the whole agreement state system that would disenfranchise --

CHAIRMAN CERQUEIRA: Yeah, but the agreement states had three years upon which to act, and during that time they can operate under the ole rules and, you know, even under the best case a lot of them will.

DR. WILLIAMSON: Well, they can't -- for three years they can, but they're going to start implementing the new rule, and some of them will implement the new rule if it's implemented in toto,

and that is going to propagate to the other 32 states potentially this error.

So I actually think the most rational thing is to keep that part of the old system intact until a new part can be thought out and implement the rest.

CHAIRMAN CERQUEIRA: Ruth.

MS. McBURNEY: But during that time if the Committee's recommendations get adopted by the staff and put forth as a proposed rule, there will be parallel rulemaking or parallel rule development among the -- for the suggested state regulations that will be out and available to the states along with that in that time frame.

DR. NAG: I think to be realistic it's going to be at least two or three years. I mean, nothing happens in one year. I mean as a minimum, all that we talked about realistically look at two or three years.

DR. WILLIAMSON: So I think if there's a concern with nuclear medicine, since that's uncontroversial, more or less, that could be exempted, but I do think in the therapy area, why propagate this error unnecessarily?

CHAIRMAN CERQUEIRA: Niki?

DR. AYERS: Well, I would point out it isn't as simple as keeping the old training or Board certification training experience requirement. If you keep those, they will now refer to sections that no longer exist.

MS. McBURNEY: That's right.

DR. AYERS: You're going to create a real problem.

CHAIRMAN CERQUEIRA: Niki.

MS. HOBSON: Yeah, I'm just wondering what the practical impact on patients that this is going to have. Now, I mean, just sort of visualize. You know, we're stringing this out over two or three years. Well, people are going to change jobs. They're going to die. They're going to retire. Are we going to be left with enough people out there to provide, you know, these essential services?

I think that the holes will just get bigger and bigger, you know, unless we do something to kind of plug the gap until we can get the new rule.

CHAIRMAN CERQUEIRA: Richard, and then let's go back to Jeff's motion because if we're going to get out of here on time, we'll have to.

DR. VETTER: In response to Niki's comment, I think the greatest impact would be on a

licensee who needs to hire a new RSO, and that new RSO, if they aren't an RSO on some other license, they have to become approved as an RSO, become qualified under the new rules, and if they're Board certified or not, they are going to have to go through the process of filling out all of the paper work and so forth.

So the licensee in effect would hire a new RSO who cannot be approved on the license until they've gone through that entire process. It's going to be a problem for licensees.

DR. AYERS: Yea, I don't think it bars people, but it's a process issue, and the alternate process is more lengthy than --

CHAIRMAN CERQUEIRA: Jeff, could you restate your motion?

DR. WILLIAMSON: Yeah. My motion was that the ACMUI recommend to the Commission that the implementation dates of new Part 35 be staggered so as to delay the implementation of training and experience sections for authorized nuclear pharmacists, authorized user/radiation oncologist, authorized medical physicist, nd radiation safety officer until such time as a revised rulemaking can be completed to rectify the problem.

CHAIRMAN CERQUEIRA: Now, I think some

people had some issues with that just in terms of, you know, the staggered implementation.

DR. WILLIAMSON: Well, I think it's important to -- you know, the message is come up with some administrative strategy to try to retain the old system until --

CHAIRMAN CERQUEIRA: So could we make --

DR. WILLIAMSON: -- the rule can be fixed and --

CHAIRMAN CERQUEIRA: -- the motion sort of more general rather than trying to give them a specific solution for it?

DR. WILLIAMSON: Okay. I'll rephrase it then. The ACMUI recommends that the Commission retain the old training and experience requirements for authorized nuclear pharmacist, authorized user of 35-600 materials, authorized medical physicist and radiation safety officer until such time as a rulemaking initiative can be implemented to rectify the problem of training and experience requirements.

CHAIRMAN CERQUEIRA: Can we get comments from people that would have problems voting positive for that?

MS. McBURNEY: I think I still think that you're going to have problems in doing that as Bob

Ayers mentioned, referencing parts that don't exist anymore. The requirements for diagnostic authorized user are actually going down, I believe, on the number --

MR. HICKEY: Yeah.

MS. McBURNEY: -- of hours of training, and you --

DR. WILLIAMSON: But that's excluded from this.

MS. McBURNEY: Let me finish.

And the -- no, it's not excluded.

DR. WILLIAMSON: I just excluded it in my motion.

MS. McBURNEY: I didn't hear that.

DR. WILLIAMSON: Well, I focused, just to repeat it, for authorized nuclear pharmacist, authorized medical physicist, authorized user in 35-600, and radiation safety officer. That's the scope of my motion.

MS. McBURNEY: And it's going to leave some doubt and confusion among the states as to what rules need to be implemented, and in making their rulemaking, do they use the old criteria or the new criteria, and so forth?

DR. VETTER: The NRC is going to do what

they have to do to implement the new rule. I would vote in favor of this motion to send the message, and they're going to do what they have to do.

DR. WILLIAMSON: I think the basic message is think outside the box and see if you can come up with some way and solve all of these administrative problems that Ruth and Bob have mentioned.

CHAIRMAN CERQUEIRA: But if you make that motion without putting in specifics and delaying the implementation of portions of it, which I think are going to be controversial, I think that will send them the message.

And I think we also agree that maybe Richard and I should call Commissioner Meserve and talk to him to see what other options are available.

DR. WILLIAMSON: I think, you know, we're not the legal experts. It's their job to figure out how to do this.

CHAIRMAN CERQUEIRA: Right.

DR. AYERS: I would comment I think you're addressing the wrong issue there with the training and experience requirement. It's the Board recognition that's the issue, and if the Boards had to be vetted against the existing requirements, I think they'd have the same problem.

DR. WILLIAMSON: Well, that's correct, and so that's why I said leave it. Right now the existing training and experience requirements don't create that dilemma. That's why I phrase the motion --

DR. AYERS: Nor do the new ones. It's the recognition process that's the problem.

DR. WILLIAMSON: But the old regulations don't require a recognition process. That's why the dilemma is not raised. It's avoided by my motion.

CHAIRMAN CERQUEIRA: Well, the NRC and this Committee because we had a lot of input into it.

So state your motion again, Jeff.

DR. WILLIAMSON: Okay. The ACMUI recommends that the Commission retain the existing training and experience requirements for authorized nuclear pharmacist, authorized medical physicist, authorized user of 35-600 modalities, and radiation safety officer until such time as a rulemaking initiative can be completed to rectify the problem of recognition of the Boards as pathways for achieving this status.

CHAIRMAN CERQUEIRA: We should probably get a second on this new motion.

DR. DIAMOND: I'll second that.

CHAIRMAN CERQUEIRA: Any further

discussion, which I hope -- okay. So we should vote.

All in favor of Jeff's motion?

Opposed?

Okay, and you abstain? Okay.

Yes.

MR. LIETO: Dr. Cerqueira, are you and Dick still going to plan on conversing with the Chairman?

CHAIRMAN CERQUEIRA: I would leave that up to the Committee. If the Committee feels that would be appropriate and helpful, okay.

DR. WILLIAMSON: I think you should.

CHAIRMAN CERQUEIRA: Okay. Now okay. We can do that.

All right. Bob, thank you.

All right, John. So I guess we've got actually three items left. The update on the new IVB devices undergoing current review; security of radioactive materials by Cathy Haney.

Has Cathy been in the audience? She's been her in all of this.

MR. HICKEY: Could I request that we have Cathy Haney go next since she's on a tight schedule and --

CHAIRMAN CERQUEIRA: Sure.

MR. HICKEY: -- I'm going to be here for the remainder of the meeting?

CHAIRMAN CERQUEIRA: Sure. FCSS, SSSB. What does that stand for?

MS. HANEY: It stands for Fuel Cycle Safety and Safeguards, and the Safety and Safeguard Support Branch.

(Laughter.)

MS. HANEY: And then I can tell you about the next tier down, which are the sections, but I think that's probably good enough.

CHAIRMAN CERQUEIRA: Okay. Well, that's god, Cathy. Welcome back.

MS. HANEY: It's a long way from the Division of Industrial and Nuclear Material Safety.

PARTICIPANT: Actually, do you have an overhead?

MS. HANEY: Yeah, and I think my presentation will be a lot less controversial than the last ten minutes that I just heard. So you all can sit back and enjoy for a few minutes.

DR. WILLIAMSON: Sort of like old days, huh?

MS. HANEY: Sort of like old days, right.

DR. DIAMOND: You've never been

controversial.

MS. HANEY: No, never, never. It was so nice to be sitting on that side instead of up there where John usually sits.

What I want to talk to you about today is mostly this is just an informational presentation, and it's maybe a little bit of a look into the future of where the medical and the other materials licensees may be in two to three years.

So this is I'm just kind of planting a seed, and also just since you are representatives of NRC, if people know, you know, that you're on the Advisory Committee and they say, you know, "What's NRC doing about security at the nuclear power plants?" it will give you a little bit of -- a couple of tidbits of information so that you all can answer that question.

I have a long list of things to talk about, but it really will not take me that long. I just want to point out what the NRC mission is, and you're so used to hearing about safety aspects, as I was when I was in the other division, and now that I'm in Fuel Cycle, it's all of a sudden there is another side to NRC, and that's the safeguard side. So we'll touch on that for a second.

Just review some of the security regulations and some of the aspects of a security program, and what I'm going to really be talking about is coming from the reactor world, but when you sit back and look at them, they apply to all of your facilities when you look at security and safeguards as an overall issue.

I'll tell you about what we did immediately following September 11th, and what we've done, some long-term actions, and then talk about where we're going from there, and then just touch real briefly on what are the implications for this Committee, and in two years what will I be talking with you about, and I'll be back in the controversial seat. So that's why I'm starting now.

So as far as the NRC mission goes, I think everyone realizes that it's to protect the public and promote, but once you get beyond that first line, people are not as familiar with that second line, which is we really do have a role in promoting the common defense and security aspects of use of byproduct source and special nuclear material. So it is much larger than just a safety and worrying about public dose and occupational dose.

If you look at the regulation of security

aspects, it's very similar to what you see with the safety aspects. First, we're regulating through a licensing. There is inspection and oversight.

Now, in your particular hospital settings or university settings, about the only regulation that you're going to look to is Part 20, Section 1802 that has to do with security of material, which is a little short, two or three liner in 10 CFR.

When you get into some of the larger facilities, you're looking at whole sections of 10 CFR, and I don't see you going there. So don't get panicked thinking, "Okay. She's really setting me up for two years." I'm really not.

But we occasionally do rulemaking in the security area. If we were going to change regulations with regards to -- I mean, if we were going to change our posture about security of licensed material, we would be looking to possibly rulemaking.

There is a lot of research that goes on in this area, especially post 9/11. Our research in the security aspect has also increased, as well as our intergovernmental coordination.

I mean, we always in this area had a lot of coordination with the FBI, with CIA as far as looking at intelligence information that was coming

through, but now with the Office of Homeland Security, that's increased drastically.

We have also reached out to a lot of the other intelligence communities, working closely with. We are talking about possibly putting some staff a couple of hours a week down at the FBI building and long term maybe even down at the CIA.

So we are looking at really doing some outreach with the other government users, and what we're looking at this is really from a national infrastructure standpoint. The government as a whole is deciding what area to put their resources into to protect. There needs to be some hierarchy of identifying what are the key infrastructures that need to be protected, and that's really -- NRC is playing in that area. So I want you to know that we are particularly involved in that.

If you're looking at a safeguards and security program, there are a couple of key terms that you need to look at, and I'm not going to go through all of this in depth, but the first one that I want to mention is design basis threat.

And the reason I want to mention this to you is this is something that we will be considering relative to larger material licensees, and basically

what a design basis threat is is identifying the key components that we want a facility to protect against, and then once the NRC would identify those, this is turned over to the licensees, and then the licensees develop a security protocol for doing it.

Typically it's a denial strategy, which is basically keep the bad guys on the other side of the fence. So it's something very simple.

We are doing a top to bottom review of our security program, the safeguards program. I'll get into that in a few more minutes, but one of the things that we'll be looking at is the design basis threat and whether what we currently have should be changed in light of the heightened threat environment and also who should the design basis threat apply to.

Right now it really only applies to reactors and to our very large fuel cycle facilities. So it's a very small population. But should certain aspects of that design basis threat apply to a hospital, apply to a university?

And if you're thinking, "Okay. That sounds great, Cathy, but what does that mean real world?" you know, when you take it down to the hospital setting, I mean, maybe that's putting up some extra vehicle barriers to keep like a truck from

approaching the facility very close. It's just looking at your physical layout to see if there are any changes that would need to be made.

When you're looking at security programs, it's really broken into three areas. One is physical security. Second is personnel security, and then information security.

There's been a lot recently on the Internet about the information security, and this has to do with vulnerability of access to modems and your communications systems, and I'm sure individuals at your facilities are really looking at this already, but again, it does go beyond just a nuclear environment when you get into the information security.

And then we talked a little bit about the NRC oversight program already, that it is in a way similar to what you're familiar with.

And the last item is security levels, which is probably something that you have not heard before mostly because it hasn't applied. And again, I'm not sure that I would if I was going to crystal ball it say that it would apply to you, but let me tell you a little bit about them.

Right now NRC has three security levels.

Immediately following the terrorist attacks, we went to our highest security level for our licensees, which is a Level 3, and this has the licensees increase security at their site and make changes to really all of their physical security, their background checks on personnel, as well as their information security.

There's an effort underway at the government level to take all of the different threat levels or security levels that each agency has and go to some type of uniform level. This is an effort that's underway under the Office of Homeland Security. And as a result of that, you know, when one agency says we're at one level, the other agencies are at similar levels.

So there will be more to come on that. It's just in the initial stages at this point, but just be aware that there are different security levels that NRC does have now for some of its facilities.

I think what I'm going to do is skip over the next couple of slides so that I can keep you on schedule here. I've been responsible for keeping you late before. So I don't want to be responsible today.

Let me tell you what NRC did immediately following the attacks. The first thing is we activated our Emergency Operations Center, and that

was activated within a couple of minutes, and we went to 24 hour staffing on that particular area.

We had our executive team, which is a representative from each one of the offices in NRC, like the Office of Nuclear Material Safety and Safeguards; Marty was there, which is our Director; Office of Nuclear Reactor Regulation had their office director there; and the Chairman of the NRC was also there. And we staffed that for 24 hours.

Our first step was to issue a threat advisory, which took all of our licensees to their highest security level, and then subsequently we've issued updates to those threat advisories. I think all total we've probably issued in the 20 to 30 type of range of advisories, and for various reasons.

If we saw a change in the threat environment, we would inform licensees or if there were certain actions we wanted licensees to take, we would issue an advisory. And most of the advisories went to the power reactors.

There were some -- I think there was one advisory that went to all materials licensees. There were some where we went to just the large material licensees, those with emergency plans. But these were typically the licensees that already had a very formal

security program in place where we thought that they should make some changes in that particular item.

If with the larger licensees we did contact them and discuss what actions they had taken in response to the advisories, we maintained constant coverage of monitoring the intelligence traffic to see if there was anything changing that we needed to know about and whether we needed to increase or decrease security at our sites, if there was a specific threat against any of our reactors.

We also coordinated with the states, and we did have someone down at the FBI's what's referred to as SIOC, which is the Strategic and Information Operations Center. And then I'm sure when you came in today you saw a different security system than you had previously seen here. So, I mean, even in house we increased our security.

Post 9/11, and this is where we start to look at where will we be going from here, and you guys, some effects on your particular licensees. We were looking at augmenting licensee's capabilities, and this is recognizing that pre-9/11 there was a certain threat environment that our licensees were expected to protect against, but then post 9/11, we did want them to increase that security.

So we're taking it up a notch or two or three or four, depending upon who you ask, but we are increasing licensee security requirements to what the Commission believes is prudent in light of the current threat environment.

We also have coordinated federal assets with other government agencies. Two are noted up there. One is the Coast Guard and the Combat Air Patrol. Depending upon what action we were taking, if it was gathering information from these other agencies or providing information from our sites to these other agencies, we were doing significant outreach to the other federal agencies.

I've mentioned that we are doing a top to bottom review of the safeguards program, and this is something that is very much -- most of the work will be done in fiscal year '02. There is some that extends out into '03, and then there's a very little bit that goes into '04, but the thought is that the majority of the work will be done this year and next year.

There are a couple of things that we're looking at, is looking at that design basis threat to decide if any changes need to be made to that. We're looking at vulnerability assessments at the sites

where we're actually going out to some sites or having contractors go out to sites and look at the particular sites and look for what are the vulnerabilities, and given the increased threat environment, do adversaries have better access to those sites typically referred to as critical target areas? And are there any -- we have not gotten down at this point to looking at your small hospitals. The majority of the work is in the reactor area in the fuel cycle arena.

We may be looking down into some of the large irradiators, and again, the focus is on risk. What risks do the specific facilities pose, recognizing that from the standpoint of the medical facilities, you've been complying with 20.1801, looking at security of material all along. So with the hope that you would just keep doing what you're doing and consider any of the increased threat environment if there is anything that you would need to make changes.

There may be possibilities for legislative changes in this particular area. There are several Congressmen that are very interested in what NRC does. So it's possible long term you could see some changes in that area.

Also, there will be some changes, I

believe, in the interagency coordination aspects, again, just trying to work together. We're all trying to work together as one federal government to come up with a position that would be uniform between the different government agencies.

As far as what's going on in the threat world, because if you listen to CNN, you hear a lot about it, hopefully we'd like to hear about it before it hits CNN, and that usually works.

There's one case where I was driving home from work and heard something on CNN. It was like when I left work everything was fine, and an hour later what am I hearing on the public radio?

Once 9/11 hit, we asked all of the sites to report suspicious activities to us, and to be quite honest, we had hundreds of reports in, and some of them were fly-overs where you'd have small planes flying over the reactor sites at very low levels, caused some concern because there really was no reason for the planes to be down that low.

You know, when you go back and look at them, you know, they could not track where the airplane came from. So it makes you wonder as to what's going on.

A lot of strange people. It's amazing the

number of people that feel it necessary to take pictures of nuclear power plants.

(Laughter.)

MS. HANEY: So now those people have found it into our database of the number of incidents in that particular area.

When we got an unusual case, it was typically reported to local FBI, and local FBI would go out and investigate it if it was something that was deemed crossed a threshold of this seems awful strange; maybe we should look at it.

And obviously, there were some differences on some of the risks that were posed. I think there was one case where we had someone being interviewed by local FBI that was just two tourists that happened to want to be taking a picture of the lake and then on the other -- they didn't realize that on the other side of the lake was the nuclear power plant. So there were, you know, things like that.

But in some of the fly-overs, it led you to be a little bit more concerned about what was going on.

All right. Flip this one.

Okay. Surveillance and planning, and the reason that we looked into this particular area was

that, you know, it's obvious that the September 11th attacks did not just occur, and there have been multi-year surveillance going on, and this is why it's important in your facilities to -- you know, the constant attention that you do pay to security because if something is going to happen, it's usually not just, you know, I decided to do something wrong today. It's something that someone may have been thinking about for a while.

And looking at different systems that you can have in place with regards to this surveillance information collection, just sensitizing people in the departments to be aware of any unusual activities.

Your security system challenges, I mean, you have security systems in the hospitals for reasons beyond the radioactive materials, but again, making sure that in your particular departments that you are involved in decisions made with regard to this security because it does have implications for the radioactive material.

This insider infiltration sounds awful serious in the area where you are, in the reactor areas, the fuel cycle facilities. It is a big concern, but to bring this down into, you know, the world of the university and the hospital, this is the

misuse of the radioactive material where you're, you know, putting in someone else's food or something like that.

I mean, we've had incidences over the year. so it really does apply, and I think what I'm trying to say is, well, you know, most of this program, security and safeguards program is set for the power plants and the fuel cycle facilities. It really does have implications into the university setting and the hospital setting.

Okay, and then the last one is really what are the possible implications for the material licensees. What will I be back here talking to you about in two years?

And these are my crystal ball, I guess, if you want to refer to it that way. One is the vulnerability analyses.

As I said, right now we're really not focused down into the university or into the hospital setting, your small community hospital setting.

It's possible that long term that we do start looking a little bit closer at what are the vulnerabilities at the hospitals, and when we would approach it from a hospital setting, we'd start with the higher risk sources as compared to your community

hospital that's only doing 35, 100, and 35, 200.

There may be some statements that come out from NRC with regards to increasing security at your sites. We have proposed what we've called interim compensatory measures for the larger licensees, and it's possible that long term that we may be proposing some security measures that would be at hospitals.

Again, you're not on the top of the list right now, but long term, you know, we would be looking at these areas.

And then as we do go on and make changes in our safeguards and security regulations, there may be some of those changes that would affect your facilities, and that would be something that we would be coming back to talk to you about.

So as I said, these are long-term changes. Obviously when we are doing this top to bottom review of the safeguards and security programs, we're thinking of all licensees. So you're not lost; you're not forgotten.

We are using a risk approach, the larger licensees, higher risk licensees first, but recognizing that some of the changes that come out of those programs could have implications to the medical setting.

So that is the quick overview of the safety and safeguards and what NRC has done post 9/11. I'd be happy to answer any questions, just not about Part 35.

(Laughter.)

MS. HANEY: I had to get that in, Jeff.

DR. VETTER: We kind of laughed when you mentioned people taking pictures of nuclear power plants, but we've had people taking picture of our oxygen supply at our hospital, of our own nuclear -- not nuclear. I'm sorry -- our own power plant. We have two, one for our clinic, one for our hospital. And so we're getting a little bit -- some of these have been investigated by the local law enforcement, and you know, it's innocent enough just like you've mentioned. Nevertheless, you can't help but get a little bit paranoid.

And then because of my own naivete, I've learned today that the location of where we store our brachytherapy sources and our nuclear medicine generators and all of that is on ADAMS. It's there for the world to see, and I didn't know that because our information security is so tight I can't get to ADAMS. I can't get through the firewall. I can get E-mail, you know, and all of that. You can get out,

but when it comes time to getting back in, our firewall is so secure I haven't been able to go up to ADAMS.

I'm going to work on an alternate pathway, but what I'm really getting at is I hope I'm not the most naive RSO in the world. I would submit that most RSOs don't know that the location for the storage of their radioactive materials is on ADAMS.

If they did know, they might think a little differently about the security of their area. And in fact, if I knew that in my last license reapplication, broad scope license application, which we turned in in December, I might not have furnished room diagrams. I would have challenged the NRC to have Enforcement or Licensing come out and look at it rather than give you a room diagram showing the location.

I'm just a little concerned about that, and the challenge I would have for you is, or the NRC, whomever, is to notify radiation safety officers that, in fact, all of this information is on ADAMS in case they didn't know about it, and you know, they may want to heighten their own awareness of security issues because of that.

MS. HANEY: Well, I think that's a good

point. Early on NRC took down its Web site completely.

DR. VETTER: But they didn't take down ADAMS, did they?

MS. HANEY: Well, there were a couple of days where it was down. Everything was down. You couldn't access anything on NRC because of just some concerns about what information was on there.

Bit by bit the Web site has gone back up, but I think you're correct about the ADAMS issue, and that would be one thing. I will take that challenge, and I guess as you're interacting with your associates, you know, also to make them aware because that's a good way of getting the word out, sometimes better than what NRC is doing.

And I think it is good to think about what information you are sending into NRC, and it's time to question it because, you know, information that we didn't used to worry about pre 9/11 coming into the agency, and then the aspect of NRC trying to share the information with the public, to be open. Things have changed, and I think you raise a very valid point.

MS. WAGNER SCHWARZ: Cathy, is there some way that that portion of the information can be withdrawn and not -- I mean, because of security

reasons, not made available?

MS. HANEY: We can look into it. I would say it certainly is a valid concern. There are ways that you can take information out of ADAMS, such as that.

So I mean, I'll take that as an action item for John.

(Laughter.)

MS. HANEY: John's over there saying you like that. You just vote me on that one.

But I think it's something that we probably should look into and consider.

CHAIRMAN CERQUEIRA: David.

DR. DIAMOND: Cathy, thank you very much. If memory serves, I think I'm the one that suggested that we have this little briefing, and I found it very, very informative.

I would like to echo what Dick said, which is that certainly we're not the highest risk licensees, but at some point it would be useful to send out some general memorandum to the hospital based licensees just to gently remind them regarding the importance of these issues.

My question is without giving us any information which would make you uncomfortable, just

stemming from some discussions we had earlier today with Dr. Frant, has there been any concern in the government of prior credible threats about folks, bad folks, trying to avoid these very high risk targets and starting to look into these dirty bomb issues or dispersal of radioactive materials, such as Iridium-92 or cobalt?

Can you tell us if that's been a credible concern or is it just our paranoia reaching down?

MS. HANEY: Well, I guess for as much as I can say, I guess there is a concern obviously looking at the Washington Post and the Washington Times. There have been numerous articles about dirty bombs, and I'm sure in your local newspapers you've seen some, and there's been some reporting.

So I think it's fair to say that it is a concern and something that people are looking at. Beyond that I'm not sure I can give you much more information on that.

CHAIRMAN CERQUEIRA: Ruth.

MS. McBURNEY: Getting back to Richard's comments and the fact that license information is on ADAMS, in our state once we send out our security advisories to our major licensees, we had some calls from one of the major manufacturers there in the state

who was concerned that the location of their radioactive material was available under open records.

We don't have that same information on our Web site, but I did assure him that we are looking at whoever. We take the names and so forth of people who come in to look at files and have been a little more aware of who's looking at what in that case.

CHAIRMAN CERQUEIRA: Richard.

DR. VETTER: Cathy, I wanted to also thank you for being here. This has been very, very enlightening. You said you didn't have much to offer hospitals relative to vulnerabilities, but of course, the obvious one is the room exists; the storage facilities exist. Hopefully they've all got the door locked.

But we're from, especially in the hospital environment, from a value system that we find it very difficult to think like a terrorist, and so if in your studies of this issue, if you have come up with vulnerabilities that could, in fact, be applied to a hospital environment, I think it would be really worthwhile to share that with us.

MS. HANEY: And I think that's the long-term intent that we would be doing that. Obviously if we had reason to believe that there was a threat

against a hospital, we would make the hospital aware of it, and it would not be a delay, you know, factor.

What our tendency has been, we have the routine review of the intelligence traffic, and if a facility by name were to come across or even by category, we would notify that category.

But beyond that, you're right. As we identify vulnerabilities at different sites, there are some items that are common to the hospital setting, and we would certainly share that with you.

And what we are looking at also is going beyond. Obviously our focus is the radiation aspect of the material, but at some of our sites, there are certain chemical hazards that NRC does get into the oversight with because it is inherent to the processing of the radioactive material.

So we are looking even broader than just the radioactive material aspect.

CHAIRMAN CERQUEIRA: Other questions for Cathy?

If not, I'd like to thank her for coming back to the ACMUI.

MS. HANEY: You're welcome. It's always a delight. I like coming back here.

DR. DIAMOND: We miss you.

MS. HANEY: I miss you guys, too. I really -- and I wanted to come to the Commission meeting yesterday. I had it on my calendar, and I couldn't get down there. So I felt better because I thought I'd get to come down and say hi today. So I'll see you all when you come back.

DR. DIAMOND: Maybe we can get you back for the next round of rulemaking.

MS. HANEY: I don't know.

(Laughter.)

MS. HANEY: Is that what I want? You need me back? Okay. Well, they'll just transfer me down the hallway. Actually all I am is around the hallway. So they'll send me back around. So whatever I can do, please let me know, and take care.

CHAIRMAN CERQUEIRA: Again, thank you.

We have several items on the agenda. People wanted to try to end by three o'clock. So we may try to keep some of these brief rather than in detail, but obviously if there's need for discussion we'll do so.

John, do you want to update us on the new IVB devices?

MR. HICKEY: Yes. I will be brief.

First of all, I want to say that in

licensing and providing guidance on IVB, intravascular brachytherapy devices, the Committee has provided invaluable advice and suggestions, and our approach has reflected that advice, and we think it has held up very well.

A couple of areas, for example, was in one of the questions was use of the procedures in ways that were not specifically reviewed by FDA when FDA granted approval of the devices.

Another example is the physical presence issue and who should be physically present during the procedure. We think the approach we've used has held up well. We've gotten some questions clarifying, you know, do you really mean an authorized user is actually supervising the use of the material, and we would say, yes, we really do mean that.

But we think the approach has held up very well and will continue to hold up for things that may come in the future. I don't think we're going to have to come back to the Committee for some things that we, you know, didn't anticipate in these initial approaches, although, you know, you never know what we may need to come back to the Committee for.

As far as future devices, there are a couple it's our understanding are in trials, but we

don't think they will raise new issues. They still will use solid material is my understanding. It might be a coded (phonetic) source rather than a sealed source, but the technology I don't think will pose any new issues that we haven't discussed, but if they do, we can come back to the committee.

There has been talk of -- I shouldn't say just talk. There have been proposals and prototypes of liquids and gas, but I think those are farther away, is our sense, but that is always a possibility. I don't think they will raise issues that aren't covered by the existing guidance and positions we've taken.

So that's basically a summary. I think so far we have a success story on IVB.

CHAIRMAN CERQUEIRA: We have a number of approved devices. How many new devices are currently under FDA review?

MR. HICKEY: Well, one is a coded material, but it's still basically a sealed source. Another is a high dose rate type source that could be used in large vessels, using a sealed source.

There have been other discussions of liquids and gas, but I think a lot of those have been dropped, but there may be other ones out there that

I'm just not aware of because they're farther down the road. They're farther on the way.

DR. DIAMOND: I was just going to clarify the point. One is a wire foil which is radioactive. So a kind of variation on the theme of a solid source.

The second one is an extant source design in which the delivery system is modified in a very clever way so as to change the depth dose characteristics. That's the one that's addressing the larger vessels.

DR. NAG: I'd be interested in that. I would like to just make a couple of comments, if I can have the line.

Now, I think when intravascular brachytherapy came in, it was but in a separate technical emerging technology because brachytherapy was used as a basis for intervention in developing for cancer and required different consideration, and they used different technology.

But I think we have to reexamine those issues because it's true that brachytherapy is normally used for treatment of cancer, but brachytherapy has been used for many years for prevention of non-cancer things like halite (phonetic), iridium, and they have the same radiation

safety requirement as that for cancer brachytherapy.

So, you know, the first argument about placing brachytherapy in a separate category, you know, doesn't hold.

Through the medical consideration for interventional brachytherapy is different from brachytherapy at other sites, but here are medical considerations at individual sites, like brain. When we started doing brain, we had entirely different considerations. When we went to prostate, we had different considerations. Eye had different considerations, and the specialists from these various sites worked in conjunction with the authorized user to implant radioactive source at these sites.

So how is that different from a cardiologist working in a vessel, working with an authorized user? If the radiation safety issues in interventional brachytherapy are different from the regular brachytherapy for cancer, the same regulation should apply. So why have a separate category for interventional brachytherapy and a separate emerging under 1,000?

The other thing is interventional brachytherapy uses separate technology from cancer brachytherapy. Again, that's not true because for

each type of interventional brachytherapy you have in conventional brachytherapy and will give you some examples.

And the radiation safety issues --

CHAIRMAN CERQUEIRA: Subir, again, I don't mean to -- this was sort of added to the agenda, and just for the sake of time --

DR. NAG: I just have my recommendation for that.

CHAIRMAN CERQUEIRA: Okay.

DR. NAG: And therefore, I think -- but these are important -- my recommendation is to eliminate the special consideration of intravascular brachytherapy as an emerging technology and place equally interventional brachytherapy in the corresponding brachytherapy category, and all the radiation safety regulatory requirements as needed for other brachytherapy procedures should apply for interventional brachytherapy and that will give you these examples.

Under the guidelines you have remote HDR, the Cordis, the same as your manual iridium. Novoste is the same as your strontium eye brachytherapy. A new liquid Radiance is the same as your gliacyte which is being used for brain tumors.

And the other thing is many of these new technologies that are being developed for brachytherapy for interventional brachytherapy is also being applied for cancer brachytherapy, like the beta HDR development guidance is being multiplied and used for intraluminal HDR for biliary and esophagus. The check developed for interventional brachytherapy has been used for bronchial radiation.

So it doesn't make any sense to have a different regulatory guideline for interventional brachytherapy when you are using the same equipment and the same category for brachytherapy elsewhere.

And again, you are having an unintended consequence when you substitute the "or" or the "and" because now you can have interventional brachytherapy performed by the cardiologist with the authorized user or the physicist.

So basically what you did is that it required a signature of your user without their involvement in many cases, and therefore, you can potentially compromise radiation safety.

I don't want to go into all the details, but you can have similar examples at almost every site, and I believe this issue has to be reexamined.

CHAIRMAN CERQUEIRA: Well, I guess in a

sense by putting it into the emerging category was to sort of delay it, and I think we're getting to the point where some of these things are out there and, you know, as we know, there is a lot of work going on between the intravascular -- the people doing intravascular brachytherapy, the oncologists and the cardiologists.

You know, again, I'm not sure that this is a time for us to take action on this, you know. The rules, we had a lot of discussion and put it into the 1,000 category. I think the Commission recognizes that there are issues related to, you know, safety as well as who's doing it, and I think the fact that they've appointed an interventional cardiologist to the Committee sort of recognizes that, and I think there's preparation to do this.

DR. NAG: Right, but the thing is if you're having a different rule and you are using the same brachytherapy for interventional and you have a separate rule when you're using it for other brachytherapy, that doesn't make sense. It has to follow.z

CHAIRMAN CERQUEIRA: Jeff?

DR. WILLIAMSON: Well, I actually think that there's a contradiction in what you're present.

To argue that the Novoste and the Cordis system be treated as manual brachytherapy sources, as you do, and actually reduce the regulatory burden because there is no NRC requirement that either a physicist or physician be present when the sources are put into the patient.

So you know, there certainly are standards of practice in radiation oncology that are independent of what NRC says. But if the best Cordis system were treated strictly as manual brachytherapy, there would be no requirement of physical presence whatsoever in the operating room. So now there is.

So you know, to say, you know, your two wishes are inconsistent -- to say there should be an "and," physicist and authorized user and should be treated as a 3400 is a contradiction.

DR. NAG: Then you're going out for the HDR. For HDR you have the N, and in an HDR application, then you need both. You need an HD -- for HDR application for cancer, you need the physicist and the authorized user, but when you have an HDR interventional brachytherapy, you don't need both.

DR. WILLIAMSON: But that's not what you said. You said that the Cordis should be treated as a 35-400.

DR. NAG: No.

CHAIRMAN CERQUEIRA: I would kind of leave it up to the Committee. Do you want to continue the discussion? I mean this was sort of an added item to the agenda. We agreed that because of flights we would try to basically get out of here in the next 20 minutes.

You know, I think this is a legitimate question that needs to be addressed. I think the Committee and the Commissioners --

DR. NAG: This is what I wanted to bring forward.

CHAIRMAN CERQUEIRA: -- have made a process in place and I think will come to it.

David?

DR. DIAMOND: Yeah, I don't think we need to discuss this further right now. I would convey to the Committee, however, a sense that VBT or vascular brachytherapy really heretofore has been a success story.

If you go back now two and three years when this first came out, if you remember the discussions we had about real horror stories about people using this inappropriately, off label, it going crazy, people getting hurt, public fears.

I think that we really need to congratulate ourselves once in a while and say, you know, we kept a handle on this for a while, and then starting about a year ago, we said things look like they're going well. People are practicing good, safe medicine. We took some of the brakes off. We said, "Don't be too overly prescriptive with respect to off-label use."

Since that's gone through to my knowledge, as one of the largest operators of this technology in the country, people have continued to use it with very good, judicious intent. Dr. Triparenini is probably even a more higher volume user than I, and he would, I would hope, share the same feelings.

People really have with this multiple disciplinary approach, really have been very, very good at protecting the public and preventing bad things from happening. So once in a while we do need to give ourselves a little pat on the back.

CHAIRMAN CERQUEIRA: I think we deserve it after yesterday and today's discussions on our failure with certain guidelines.

Well, this is very informative, and obviously this issue will come back, and I think we'll definitely get it on the agenda.

Thank you, Subir.

We should move along on the agenda, I guess. Joe DeCicco on the mixed doses.

MR. DeCICCO: Both sides so I can remember who I am.

This is going to be very brief. I don't even have a presentation per se. I don't have any slides or anything because all I wanted to do was update you and let you know that we're still discussing and working on mixed dose, the mixed dose issue.

And in your handout there is just a brief summary of how we've addressed the issue since the last meeting, as a matter of fact, in October.

What we have done is taken the existing regulations and kind of looked at it with a fresh eye and maybe redefined the box that we're supposed to be thinking in and used the footnote in the weighting factor table in Part 20 that basically allows the agency to use other weighting factors other than one for external dose.

So that with either a case-by-case evaluation or guidance that would be issued by the agency, some other method other than deep dose equivalent could be used for determining the external

exposure.

In your package you have a regulatory issues summary, and a regulatory issues summary is similar to an information notice that you might be more familiar with, but the regulatory issues summary focuses on a regulation and either a different interpretation that has been done in the past or to allow for a new interpretation of a policy position or a relief in burden.

And I think the regulatory issues summary that you have in your package kind of addresses the issue for fluoroscopy when using a protective apron.

The regulatory issues summary has been distributed to the state regulatory agencies for comment. It was issued to the states on January 24th, and they were given 45 days for comment.

It is pre-decisional, which means it's not out there for everybody, but the regulatory agencies can look at it and address any comments to either me or to the agency at the Web site that the states have access to.

And the comment period for this regulatory issues summary draft is March 14th. Hopefully by the end of March or very close to that date, we should have this regulatory issues summary issued and out to

licensees so that they can use this guidance that addresses the issue of that mixed exposure when using fluoroscopy and the lead apron and also being exposed to NRC licensed sources.

So that's about it. That's all I wanted to do is make you aware of. If you have any comments, please provide them to me or any other method that you say.

Yes, sir.

CHAIRMAN CERQUEIRA: Richard.

DR. VETTER: So how is the license -- if an interventional cardiologist is involved in fluoro, of course, like in most of the exposure there and doing IVB, how is the licensee to distinguish what exposure came from the brachytherapy source versus the X-ray source?

MR. DeCICCO: That's a very difficult technical issue, and it's not addressed in the regulatory issues summary per se because we didn't want to try to address all of the issues.

However, the staff has actually looked at that issue, and I don't want to state too much because I don't state policy, but from a technical point of view, the evaluation done when evaluating the X-ray exposure is probably as close to the true dose than

any other method used, and I think that particular issue will be addressed after this RIS comes out because that's a much smaller community than, say, the fluoroscopist also doing nuclear medicine.

There's probably fewer physicians doing both IVB and fluoroscopy as opposed to physicians being exposed to both source and non-source at separate times.

DR. VETTER: Okay. I understand that, and that does make sense. I mean, for the nuclear cardiologist who's also doing intervention, you can have two badges and you can sort it out easily.

CHAIRMAN CERQUEIRA: That easy, but for the IVB.

Ralph?

MR. LIETO: Boy, I've got a number of things. One, I think this type of guidance affects basically almost totally medical users, and I think that something like this, which I want to say I think it's a very good document; I applaud the summary information and so forth.

I've got just a couple of comments on it myself, but I think the point that was brought up about addressing the situation of the person who has like the cardiologist or the radiologist who does

nuclear medicine and a lot of fluoroscopy I really think has to be addressed in this.

I think to take it at one time and then come back later and revisit it I really think is sort of a disservice to this document. I really think that there's a real need for this, and I think the guidance that a lot of RSOs and medical physicists that sort of struggle with this is out there.

You know, one thing may be for consideration is the fact that you don't have to badge a worker who is not likely to get ten percent of the dose limit or you know that a cardiologist is not likely to get ten percent of his dose from intravascular brachytherapy. In fact, you could almost say that with certainty.

And I can say also it's very likely that a radiologist who does fluoroscopy is not likely to exceed ten percent of his does from his nuclear medicine activities. It's very hard to get exposed from behind that alternator.

And so I would say that as maybe a suggestion for guidance in this document is that using this guidance and assigning doses for external and internal for NRC licensees would be applicable to those situations where the licensee can document that

it is very unlikely, that it's not likely that the worker is going to exceed ten percent from his licensed NRC activities.

And I guess I had one question. Your Item No. 4 on page 3, you said that any alternative method that is used incorporating the license must be incorporated in the licensee's procedures and program.

It almost makes it sound like it's a license condition. Do you understand where I'm kind of going with this? And that it has to be instituted prior to the exposure for which an alternative method has been applied, and I'm just trying to understand why that went in there.

MR. DeCICCO: Yeah. Not to go into too much detail because of time and since it was pre-decisional, I think what we were trying to avoid is this is going to be a prospective application of the accepted -- the guidance. We didn't want people to go back to previous exposure or past years and say, "Oh, well, that exposure really wasn't that. Now we can reevaluate it."

We didn't want people to go back. We just want this to be a prospective.

It being a requirement to be documented, that was put in there primarily to avoid people

flopping from one procedure to another to fit their needs. We wanted it to be a prospective application, and therefore, you use that application as long as you feel that that's appropriate prospectively.

You don't say, "Oh, well, let me reevaluate this after the fact." And that's why that particular phrase was put in there.

MR. LIETO: Okay.

MR. DeCICCO: It was to avoid that flip-flopping or going back to previous exposure.

MR. LIETO: Okay. I thought that was kind of handled in number five already, and I just --

MR. DeCICCO: Maybe it was; maybe it was. Okay. We'll take a look at that. Thank you.

CHAIRMAN CERQUEIRA: So, Ralph, how do you suggest we go? I mean, so this is basically a draft form, and has it gone out to any of the stakeholders?

MR. DeCICCO: It's gone out to state regulatory agencies for their comment, and the comment period is up until March 14th, and then we'll --

CHAIRMAN CERQUEIRA: But what about -- I mean, has a cardiologist had a chance to look at this to give you some feedback?

MR. DeCICCO: Not licensees, not non-regulatory agencies because it's a pre-decisional.

CHAIRMAN CERQUEIRA: Right.

MR. DeCICCO: Pre-decisional.

CHAIRMAN CERQUEIRA: Would it be worthwhile getting their input as well as, you know, the health physicist community?

MR. LIETO: I was just going to say I think it would be interesting to see what, you know, like the Health Physics Society might have to say about this or, you know, have some input from some of the scientific groups, but I'm not quite sure. When you say it's pre-decisional, I don't know if there's some type of restriction in the distribution of the information from a I don't want to say security standpoint, but --

MR. DeCICCO: Well, it's not security, but it's a matter of procedure.

MR. LIETO: Okay.

MR. BROWN: Yeah, this is Fred Brown.

This document was shared with you for your comments as professionals in the field, as contract employees of the NRC, and we would appreciate your input, and hopefully it will serve as the type of input that you've proposed, but the Administrative process for this document and the time frame for it basically restrict us to sharing it with you at this

point, and we hope to have it out soon.

DR. VETTER: So how do we get our comments back to you?

CHAIRMAN CERQUEIRA: Back to you, yes.

MR. BROWN: Either through Angela or directly by E-mail.

CHAIRMAN CERQUEIRA: And what time line do we have on getting the comments back?

MR. DeCICCO: Well, the comment period is officially open until March 14th, and until it's signed, you know, I'll take comments up until I can get the final version.

CHAIRMAN CERQUEIRA: Yeah, I gather it's a situation where we're -- this sort of has an impact on certainly the users, the stakeholders being the medical community, and it would have been good to have gotten this ahead of time.

So I think all of the people that are basically representing some of these regulated communities should give input.

And can we get specific information where to send the input? How do we contact --

MR. DeCICCO: On the last page of the RIS which is the next to the last page of the document, is my E-mail address, my phone number, where you can send

comments.

CHAIRMAN CERQUEIRA: Okay.

MR. DeCICCO: Or to Angela.

CHAIRMAN CERQUEIRA: Okay. All right. Do we need any follow-up on this?

I mean we should get -- Ralph, don't you think we should get some follow-up as to how this is going to eventually come out?

MR. LIETO: I think it would definitely be welcomed, especially by the Committee, and there is -- yeah.

CHAIRMAN CERQUEIRA: So should we make it an action item that, you know, at the next meeting we get some follow-up either from Joe or from the NRC staff as to what's happened with this and some time line of when it's going to be implemented as well?

Okay. Well, thank you very much, and we'll -- yes?

MR. LIETO: Joe, is there like a time line that you guys are under in terms of having this all complete? I mean, it sounds like there might be some deadline.

MR. DeCICCO: Right now my time line is to try to get this thing signed out some time around the end of March, the beginning of April, and that was

basically a Commission request on getting this issued.

MR. BROWN: Once it's issued, it will be in effect, and it should reflect the discussion that we had at the last meeting with you about how this issue should be handled.

So although you haven't seen the draft, when you look at it, it should reflect your comments to me.

MR. DeCICCO: Yeah, I don't think you're going to see any surprises. It's just a matter of putting officially in black and white guidance that the Agency will -- guidance that is put out by the Agency for the licensees.

We didn't recreate the wheel. We just kind of looked at the wheel a different way.

MS. McBURNEY: I would note that we have adopted the similar rules to the suggested state regulations, and it's working well. We've had them in place for several years.

MR. LIETO: The only area I foresee issues are in non-agreement states --

MS. McBURNEY: Right.

MR. LIETO: -- that may not be as progressive as the State of Texas.

MS. McBURNEY: I understand.

CHAIRMAN CERQUEIRA: Okay. Thank you very much.

MR. DeCICCO: Thank you.

CHAIRMAN CERQUEIRA: We should move along here, and if we just basically skip down on page 2 of the agenda, I think we've covered the first two items that we were supposed to cover age the break.

The ACMUI vacancies, there's a sheet that was distributed by Angela to the Committee, and we're actually in fairly good shape in the sense that we've got two appointees, and it says, you know, 2001, and yet we're into 2002 and we still don't have those people on board.

And I think, John, the feeling of the discussion we had earlier is that the sooner we get these people on board, the better.

MR. HICKEY: Yeah, we agree.

CHAIRMAN CERQUEIRA: And I guess just sort of looking ahead, 2003 we have a whole slew of people who are eligible for reappointment, and we should, you know, basically send requests to these people.

And I guess now is the appointment made by the NRC? Do we normally go back to the societies that recommended these people? How are reappointments handled?

MR. Hickey: No, the reappointments can be handled internally with the Committee and the Commission if the appointees are still willing to continue to serve.

CHAIRMAN CERQUEIRA: So how soon can we reappoint people so that we, in case somebody decides not to continue on the Committee, we can --

MR. HICKEY: Well, late -- I'm sorry.

CHAIRMAN CERQUEIRA: No.

MR. HICKEY: Late in the calendar year prior to the appointment date, I think we would check with the appointees and then confirm their reappointment early in that year.

CHAIRMAN CERQUEIRA: But when would they go off on 2003? Would it be the fall of 2003 that they go off?

MR. HICKEY: Well, we didn't put months here. We'd have to check on that, but I would say six months ahead of time would be plenty.

CHAIRMAN CERQUEIRA: Well, I would say, you know, if we know that people are coming up, we should request if they want to continue, and then make it available for them to be reappointed, and if they say no, then I think we need to initiate the process.

MR. HICKEY: Yes. Well, certainly if a

member knows they don't want to be reappointed, they should advise the Commission staff immediately. I mean, you know, as soon as they --

CHAIRMAN CERQUEIRA: Well, they may not actually know the reappointment date. So I'd make a recommendation that, you know, we basically send out letters to these five people. That's a huge chunk of the Committee that basically goes off on 2003, asking them if they wish to, you know, be reappointed, in which case we can initiate the process, and that would identify, you know, clearly identify people who don't plan to come back.

Is that a reasonable?

DR. NAG: I think on the reappointment the problem is only if they don't want to be reappointed.

CHAIRMAN CERQUEIRA: Right.

DR. NAG: Therefore, you need about one year.

CHAIRMAN CERQUEIRA: At least a year.

DR. NAG: Now, if all of these people said they wanted to be reappointed, there's no problem.

CHAIRMAN CERQUEIRA: Right.

DR. NAG: But if they are not, then there is a problem. In fact, I'm even wondering. The ones in 2004, if they are spring 2004, we should start

thinking about them because there are one, two -- there are two people who are going to be rotating off, three.

CHAIRMAN CERQUEIRA: Yeah. No, I think that's very, very true.

So maybe what you're saying is the first action item is that the reappointees for 2003 should be contacted regarding their desirability to continue on the Committee, and for the people who are going to rotate off on 2004 we should initiate the process for soliciting names and nominations. Does that sound like an action item from the Committee?

DR. NAG: I think so

CHAIRMAN CERQUEIRA: Ralph?

MR. LIETO: I think it's just a consensus to the staff and go from there.

CHAIRMAN CERQUEIRA: Yeah.

DR. WILLIAMSON: I think so.

MR. LIETO: It's something you've already got in the hopper anyhow, I imagine.

MR. HICKEY: That's fine. It just seems to me it's a little early now to solicit appointees for 2004. I would have to look at how long it has taken in the past.

CHAIRMAN CERQUEIRA: Right.

MR. HICKEY: I think you're going to find this cardiology position is going to be filled within about three or four months of the Commission stating that they wanted someone appointed.

CHAIRMAN CERQUEIRA: No, no. Well, that's good, and that's -- but, again, we've kind of -- I think the Committee has been pushing to try to get this done, and so does anybody object to requesting that the NRC staff take those actions?

PARTICIPANT: It's a good idea.

CHAIRMAN CERQUEIRA: Sounds like reasonable to do.

Okay. So maybe we could have that as a follow-up item for the next Committee meeting.

Okay. So that sort of takes care of the vacancies and reappointments and people who rotate off. I just have to hold onto 2004, right?

And then follow-up discussion, ACMUI recommendations regarding interpretation of 10 CFR 35.57. John?

MR. HICKEY: We've already been through that. We don't have to have anymore discussion on that.

CHAIRMAN CERQUEIRA: That's right. Okay.

Meeting summary. Oops. We goofed upon

the RSOs and the authorized medical physicist, and we need to take action fairly quickly to try to remedy that. I think that's clearly the one thing that's come out of these two days. I think we've identified a subcommittee to deal with it.

And Richard and I will contact Commissioner Meserve to sort of see what action we can get on it.

MS. WILLIAMSON: Will the subcommittee members then just be contacted by E-mail?

CHAIRMAN CERQUEIRA: I think that would be the best way to do it, and Angela can provide the support, but once you get sort of a group mailing for the Committee, I think it would be reasonable to, you know, do whatever you feel is appropriate and, you know, perhaps copy me and John and Angela on the E-mails would be the best way to go forward on this.

Next meeting. We traditionally have been meeting twice unless there were like urgent needs. We meet in the sort of, you know, late winter, early spring and then in the fall. So the next meeting would probably be some time in October or November.

Does anybody feel we need to meet any sooner?

We have a lot of unresolved issues. You

know, we still don't know if Part 35 revision is going to be signed into law. If it is signed into law, then we still have to deal with all of the issues related to the RSOs and the authorized medical physicist and the radiation oncologist.

MS. HOBSON: How will we handle the recommendations of the subcommittee on the new rulemaking?

CHAIRMAN CERQUEIRA: I think it will be distributed to the Committee members by E-mail to get their input.

Can we have -- now, is the Committee allowed to have conference calls and what are the rules for that?

MR. HICKEY: Yes. I would suggest, given where we are, that we would plan on handling some things by conference call or E-mail, in some cases hard copy express mail if it's not amenable to E-mail, and then if you could plan on having the fall meeting as a whole.

It may be appropriate to have a subcommittee meeting or you were suggesting you may meet with the Chairman or a subgroup could --

CHAIRMAN CERQUEIRA: Well, at least have a discussion.

MR. MYERS: -- work with the Chairman or call, have a telecon. with the Chairman.

CHAIRMAN CERQUEIRA: Yeah, I think that would be preferable.

MR. HICKEY: I think the fact that this is going to be done in bits and pieces, it will be more effective and, in fact, will have to be done to a large degree by E-mail and telephones anyway because you can only do so much in a two day meeting anyway.

CHAIRMAN CERQUEIRA: Right. Now, in terms of telephone conference calls, what are the requirements? I mean, do they have to be public? Can they just be the -- since it is not the whole Committee but a subcommittee, do we need to have notice? Do we need to make it open?

MR. HICKEY: As far as I know, if it's not the whole committee, it does not need to be public. I could check that with the -- there's not time to do it right now, but I could check that with the attorney.

CHAIRMAN CERQUEIRA: I think it would be important to get that because a lot can be done on conference calls, and you know, we have no problems with it being open, but I just want to make certain that if that's a requirement that we allow that to

happen.

Richard?

DR. VETTER: I wouldn't guess that would be a problem because the subcommittee will simply be working up a recommendation.

CHAIRMAN CERQUEIRA: Right.

DR. VETTER: We can't take any action. We'll simply be writing a recommendation.

MS. McBURNEY: Right.

DR. NAG: I would suggest that most of what I hear like we would set a date or a tentative date when we are not available and when we may be available. Otherwise somebody --

MR. HICKEY: Yeah, my recollection is there are certain weeks in November that are bad because of conferences.

CHAIRMAN CERQUEIRA: The cardiology meeting, yes.

DR. DIAMOND: And in October is our society meeting.

MR. HICKEY: Yeah, there's certain weeks that we need to block out.

DR. WILLIAMSON: May we need to avoid.

CHAIRMAN CERQUEIRA: That's the end of November usually.

DR. WILLIAMSON: And ASTRO us usually what, end of October?

DR. NAG: Okay.

MS. McBURNEY: October.

DR. NAG: The ASTRO is October 6th through 10.

MS. McBURNEY: There's also the Organization of Agreement States, which will probably take not only me, but also several of the NRC staff.

DR. NAG: The RSNA, the first week of December. So some time in late October or early November is a possibility.

MR. HICKEY: I think we found in the past late October or early November is the window of opportunity.

CHAIRMAN CERQUEIRA: Right.

MS. McBURNEY: Right, Halloween.

CHAIRMAN CERQUEIRA: Well, what about the last week of October?

And what days of the week usually work best for us, John?

And we're not going to meet with the Commissioners this time. So it's just a matter of --

DR. DIAMOND: If we do a one day meeting,

we had a successful go-round last time by holding it on a Monday, if I recall.

MS. McBURNEY: That was great.

CHAIRMAN CERQUEIRA: So you want to go for --

MR. HICKEY: That's more up to the Committee. If something goes wrong over the weekend, you know, there's always the possibility that you're going to have a hard time starting up, but I know a lot of you like having the Monday meetings.

MS. HOBSON: Except for the East from the West Coast.

CHAIRMAN CERQUEIRA: So October 28th?

MS. HOBSON: That means I have to travel on Sunday.

MR. HICKEY: Talk to the Committee.

DR. NAG: I mean, if we have it the first week of October, you know, middle, the 14th, 21 or 28 October. October 28th is also -- oh, no, that's fine.

CHAIRMAN CERQUEIRA: October 28th?

MR. HICKEY: The 28th looks good, yeah.

MS. HOBSON: Yes.

CHAIRMAN CERQUEIRA: All right. So October 28th.

MR. HICKEY: So we would all have to

travel on Sunday, Niki.

DR. NAG: Right.

MS. HOBSON: Oh, these people that live close by, they just hop on a commuter.

MR. HICKEY: There's only one that lives that close.

CHAIRMAN CERQUEIRA: There's only one.

DR. WILLIAMSON: You don't think under the circumstances of having the possibility of a new rule we really should think in terms of a day and a half or two days? Almost always our meetings have been two days if you view it historically, and we've, generally speaking, filled those two days. It's been hard to get through the agenda.

DR. NAG: Yeah, the thing is if you're having it one day with all of the new requirements, most of us have to leave by three or 3:30 anyway. You know, that way you're ending up with three quarters of a day. So you might as well make it for one and a half days.

CHAIRMAN CERQUEIRA: The 28th and 29th?

DR. WILLIAMSON: Yeah, a compromise might be to do it Monday afternoon and all day Tuesday so that then we have --

DR. NAG: Yeah, but then you lose the

whole Monday morning because no one flies that morning.

DR. WILLIAMSON: Some people could fly in in the morning.

DR. NAG: Then other people have to fly in the previous night.

DR. WILLIAMSON: Yeah, that's right.

CHAIRMAN CERQUEIRA: I think Monday and half a day Tuesday is --

PARTICIPANTS: Yes.

MR. LIETO: I don't know if you want an action item.

MR. HICKEY: We will reserve this room all day Monday and Tuesday and schedule the meeting. If, upon closer, you know, to the time to the meeting it becomes apparent that the agenda doesn't support that, it can always be reduced, but I know you all want to block your calendars.

CHAIRMAN CERQUEIRA: I think we should, you know, Monday and half a day Tuesday.

MS. WAGNER SCHWARZ: Yes.

CHAIRMAN CERQUEIRA: The other thing we need to talk about is just getting the agenda for the Committee meeting, you know. This time we had the briefing with the Commissioners, and that got done on

a fairly late basis. I would really like to get, you know, to get the agenda so that we're here doing something that's, you know, dealing with issues that are coming up and trying to get as much background material out to the Committee ahead of time as possible so that, you know, our time is better spent here.

MR. HICKEY: We will do a better job of getting you the background material.

CHAIRMAN CERQUEIRA: Yeah.

MR. HICKEY: And we'll work together to have a good agenda, but part of that depends on what you propose and how many members are interested in a given topic.

CHAIRMAN CERQUEIRA: I'd say that by September 15th, which is about a month and a half before the Committee meeting, that we have a draft agenda at least together to identify the issues that have come up.

So some of these informative things are fairly nice, but if we have other pressing business, I mean, we could make those briefer, get some of the material out ahead of time.

DR. WILLIAMSON: I would suggest, too, that the staff be more proactive in, you know,

reviewing the activities of the agency and bringing items forward to the agenda for us to consider, like this group that's doing the national materials safety exercise.

You know, it so happened Ralph was aware of that, but the rest of us weren't and, you know, we have limited insight into the operations of the Commission. So I think a lot of burden falls on you --

MR. HICKEY: Yes.

DR. WILLIAMSON: -- to at least identify for us the possibilities, issues to consider on the --

MR. HICKEY: Yes. We should have done a better job on that. Frankly, we were distracted by the legislation, throwing Part 35 out.

CHAIRMAN CERQUEIRA: So what was your point about the follow-up?

MS. WAGNER SCHWARZ: On the regulatory guide, the guidance that's coming out, there are meetings that are planned, and how about feedback?

MR. LIETO: I was just going to say the same thing, that they're going to have public meetings in April, was it?

MS. WAGNER SCHWARZ: Yes, April 23rd and fourth.

MR. LIETO: And I don't know if there's going to be the need for us to get back together, not maybe physically, but either via telephone or some other means to follow up on this --

MR. HICKEY: That's true.

MR. LIETO: -- maybe a couple of times.

MS. WAGNER SCHWARZ: Yes.

MR. LIETO: So I guess maybe just an FYI to be prepared, I guess, is the best thing I can suggest right now.

MS. WAGNER SCHWARZ: It seems like it might be a reasonable thing that at least we talk by telephone.

DR. WILLIAMSON: I think so.

MR. LIETO: I would imagine if the publication of the rule is delayed, then the April meetings could get pushed back to May. Would that be true?

MR. HICKEY: I mean, anything could happen if publication of the rule is delayed. But we will do a better job of communicating with you by E-mail as to what is going on and what's coming up, and then you can get a better feel of what your response should be, you know, how you want to participate in that.

MS. WAGNER SCHWARZ: I have one more

suggestion. What about agenda items? Do you want to give us a date now that you would like agenda items sent to you?

CHAIRMAN CERQUEIRA: Yes.

MS. WAGNER SCHWARZ: So that we at least have it on the calendar for --

CHAIRMAN CERQUEIRA: I said April. I'm sorry. September 15th, but let's see what day of the week that is.

MS. WAGNER SCHWARZ: That's a Sunday.

CHAIRMAN CERQUEIRA: Well, how about Friday, September 20th?

MR. LIETO: A month?

CHAIRMAN CERQUEIRA: Yeah. Or do you want to go for like Friday, the 13th?

MR. HICKEY: Well, Mr. Chairman, if I could comment, I think we need a preliminary call earlier than that.

MS. WAGNER SCHWARZ: Okay.

MR. HICKEY: Because once the agenda is set, we prepare the background material to send out. So we need more time to anticipate what the items are going to be and what material needs to be prepared.

CHAIRMAN CERQUEIRA: September 6th? So Friday, September 6th is the deadline for having items

for the agenda submitted.

DR. VETTER: And will the staff be sending us a letter?

CHAIRMAN CERQUEIRA: A reminder.

DR. VETTER: Soliciting that or --

MR. HICKEY: Yes. Yeah, we go to the Chairman and "cc" the other members.

CHAIRMAN CERQUEIRA: Yeah, and maybe send that out --

MR. HICKEY: And we may send you --

MS. WAGNER SCHWARZ: That could come out from Angela even.

MR. HICKEY: We may send you more than one note, you know. "Start thinking," you know, and then the next note is "the deadline is."

DR. WILLIAMSON: I think we have taken the position already, haven't we at this meeting, that we want to review the regulatory guide when the next draft is available? And so there needs to be between now and whenever that happens provision made to have at least a virtual meeting over that.

CHAIRMAN CERQUEIRA: Right, and we actually had wanted to get some input into it, but the Committee is basically sitting idle. Well, not the -- the working group for the states thing, which I guess

is --

DR. NAG: Well, that's national material.

DR. WILLIAMSON: This is Volume 9 of 15.56 that I'm talking about.

MS. McBURNEY: Right.

CHAIRMAN CERQUEIRA: That's a more immediate need, right?

DR. WILLIAMSON: We've taken the position that we want to be involved. It's not an "if." I'm responding to John. I think that's already taken care of. So we need to get a copy of that as soon as is possible, and then arrangements made to have a forum for consolidating a review.

And I would think that at least a conference call among interested parties would be wise.

DR. NAG: I only want to remind the staff to make a list of all of these action items that we came up with.

MR. HICKEY: Yes.

DR. NAG: Even though you may not have their solution, at least send what the action items are so that we will remember.

MR. HICKEY: Yes, we will do that.

CHAIRMAN CERQUEIRA: And I think that

should go out as soon as we get it to people so people have an idea to see what was on the -- you know, what was discussed and what needs to be done.

DR. NAG: Yeah. That would also be something like a reminder of some of the things we may have to do with our societies.

CHAIRMAN CERQUEIRA: Right, right.

MS. WAGNER SCHWARZ: So minutes of the meeting, is that kind of what you're thinking?

DR. NAG: Not the whole minutes. That becomes too long.

MS. WAGNER SCHWARZ: Right.

DR. NAG: What are the action items.

CHAIRMAN CERQUEIRA: The action items, you know, which could be pulled out, and clearly we identified them in the transcripts. Whatever -- John, what do you think is the best way to get that out? They're not official minutes. They're just sort of action items.

MR. HICKEY: Well, I think we can E-mail it. Tim has been trying to, in addition to the whole meeting being transcribed, Tim has been trying to catch the action items, and I've got them here, too. So I think that --

CHAIRMAN CERQUEIRA: And I think we all

made a --

MR. HICKEY: -- can be done as an advanced E-mail that will be reflected in the official minutes.

CHAIRMAN CERQUEIRA: Good. Any other business?

(No response.)

CHAIRMAN CERQUEIRA: If not, I'd like to thank the Committee and the NRC support staff for getting us out on time and identifying all of the issues we need to deal with.

Thank you.

(Whereupon, at 3:20 p.m., the Advisory Committee meeting was concluded.)